Human Research ProgramIntegrated Research Plan

December 20, 2007

Interim Baseline



National Aeronautics and Space Administration Lyndon B. Johnson Space Center Houston, Texas 77058

Human Research Program Integrated Research Plan

December 20, 2007

PREFACE

HUMAN RESEARCH PROGRAM INTEGRATED RESEARCH PLAN

The Integrated Research Plan (IRP) describes the portfolio of Human Research Program (HRP) research and technology tasks. The IRP is the HRP strategic and tactical plan for research necessary to meet HRP requirements. The need to produce an IRP is established in HRP-47052, Human Research Program - Program Plan, and is under configuration management control of the Human Research Program Control Board (HRPCB).

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Human Research Program Integrated Research Plan

December 20, 2007

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1.0 INTRODUCTION AND BACKGROUND

The Human Research Program (HRP) delivers human health and performance countermeasures, knowledge, technologies, and tools to enable safe, reliable, and productive human space exploration. This Integrated Research Plan (IRP) describes the program's research activities that are intended to address the needs of human space exploration and serve HRP customers. The timescale of human space exploration is envisioned to take many decades. The IRP illustrates the program's research plan through the timescale of early lunar missions of extended duration.

The document serves several purposes for the Human Research Program:

The IRP provides a means to assure that the most significant risks to human space explorers are being adequately mitigated and/or addressed,

The IRP shows the relationship of research activities to expected outcomes and need dates,

The IRP shows the interrelationships among research activities that may interact to produce products that are integrative or cross defined research disciplines.

The IRP illustrates the non-deterministic nature of research and technology activities by showing expected decision points and potential follow-on activities,

The IRP shows the assignments of responsibility within the program organization and, as practical, the intended solicitation approach,

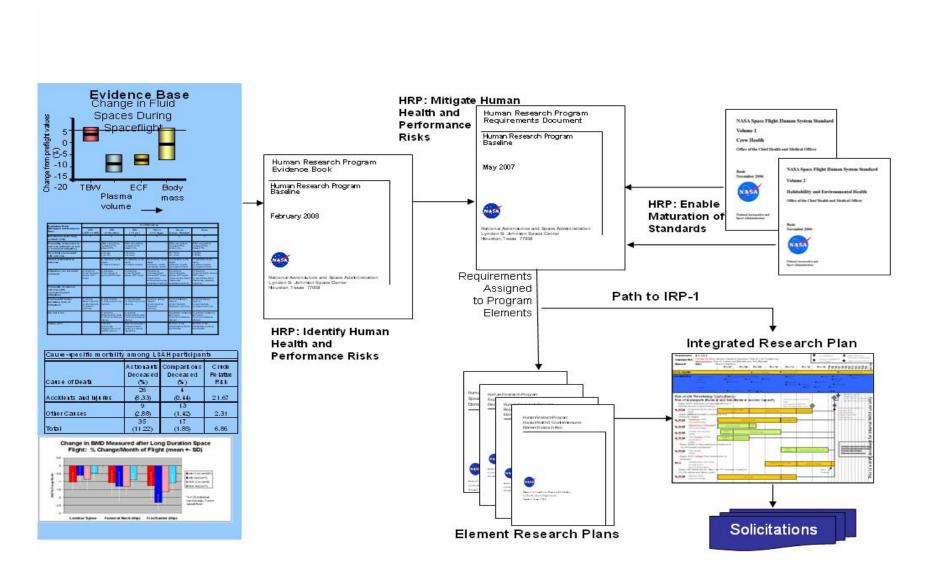
The IRP shows the intended use of research platforms such as the International Space Station, NASA Space Radiation Laboratory, and various space flight analogs.

The IRP does not show all budgeted activities of the Human research program, as some of these are enabling functions, such as management, facilities and infrastructure.

1.1 CONTEXT OF THE INTEGRATED RESEARCH PLAN

There are three foundational documents to the HRP: 1) The Program Requirements Document (PRD), 2) the Evidence Book, and 3) the Integrated Research Plan (IRP). The PRD describes the high-level requirements that the program must meet. The Evidence Book provides the scientific basis for the risks that are contained in the PRD, and the IRP describes the approach to addressing the requirements in the PRD. The relationship of these key HRP documents is illustrated in the graphic below.

HRP Requirements and Content Alignment



Graphics

1.2 PROGRAM REQUIREMENTS DOCUMENT

The HRP PRD documents WHAT risks and standards the HRP addresses.

The top-level requirements on the Human Research Program are maintained in the Exploration Systems Mission Directorate (ESMD) Exploration Architecture Requirements Document (EARD), ESMD-EARD-08-07 Rev.-. The purpose of the EARD is to translate the expectations of stakeholders, both outside and inside NASA, for the next generation U.S. Space Exploration mission, into requirements that will flow down to the implementing organizations. The EARD carries the following top requirements for the HRP:

- [Ex-0061] NASA's Human Research Program (HRP) shall develop knowledge, capabilities, countermeasures, and technologies to mitigate the highest risks to crew health and performance and enable human space exploration.
- [Ex-0062] NASA's HRP shall provide data and analysis to support the definition and improvement of human spaceflight medical, environmental and human factors standards.
- [Ex-0063] HRP shall develop technologies to reduce medical and environmental risks and to reduce human systems resource requirements (mass, volume, power, data, etc.).

The PRD decomposes those requirements into lower level requirements that can be allocated to the HRP Element level. It is comprised of two main sections, Standards and Risks;

1.2.1 Standards

The PRD requires that the HRP make recommendations for updates to the Space Flight Human System Standards (SHSS). The SHSS, Volume 1 was first baselined in March 5, 2007 by the Office of the Chief Health and Medical Officer (NASA-STD-3001, Vol. 1). It describes, among other things, Levels of Care required for human spaceflight missions, and Human Health and Performance Standards for crew members on exploration missions. Essentially, these standards define an acceptable level of risk for human health and performance associated with spaceflight. By comparing these standards with the existing evidence and knowledge base, the HRP can identify and quantify the risks associated with human exploration missions, and derive the research necessary to lower the risk.

SHSS, Volume 2 provides the comprehensive set of requirements associated with Human Factors and Habitability. These standards must be met by the Constellation program in development of each vehicle and supporting equipment utilized in space exploration. Through comparison of these standards with the state of the art in engineering design, the HRP can identify areas where research is necessary to help the Constellation program meet these requirements.

The HRP has two main responsibilities concerning the standards. In some cases the SHSS have a wide band of uncertainty. In these cases, the HRP must conduct research to help refine and narrow the uncertainty associated with the standard. In other cases, emerging evidence or knowledge may indicate that the standards are not written in a way that captures a complete set of relevant considerations. In these cases the HRP is required to inform the modification of the standard. Additional research may be required to facilitate this.

1.2.2 Risks

The PRD decomposes the top-level requirements into the specific risks and standards required to be addressed. It allocates the requirements of addressing each the risks and relevant standards to the appropriate Element within the HRP. The PRD, however, does not establish priority for the risks.

The risks in the PRD are arranged in two groups ("Table 1" risks and "Table 2" risks) based on the level of available evidence; Table 1 risks are those for which substantial evidence exists, while Table 2 risks are of concern that cannot be supported or refuted by available information. This Integrated research plan addresses each or of risks in the PRD in the priority order described below.

1.3 EVIDENCE BOOK

The HRP Evidence Book documents WHY the risks are contained in the PRD. It is the record of what the state of knowledge is for each risk in the PRD and provides the basis for analysis of the risk likelihood and consequence. As such, the Evidence Book makes these important data accessible and available for periodic review.

The documentation of evidence for each risk in the PRD is in the form of a brief review article that is aimed at a scientifically-educated, non-specialist reader. The body of each risk review contains a narrative discussion of the risk and its supporting evidence. Declarative statements concerning the risk are supported by a description of the evidence, whether published or unpublished. Relevant published references are listed at the end of the white paper. Data that are significant or pivotal are summarized in text, tables and charts in sufficient detail to allow the reader to critique and draw conclusions, especially when a published reference is not available. In a similar fashion, the authors indicate whether the data are from human, animal or tissue/cell/molecular studies. Evidence from spaceflight (including biomedical research, Medical Requirements Integration Document [MRID] data, and operational performance or clinical observations) is presented first, followed by ground-based evidence (including space analog research and non-space analog biomedical or clinical research). When evidence is from ground-based studies, authors discuss why these results are likely to be applicable in the space environment, offering available validation information for the use of these ground-based systems.

The baseline of the Evidence Book is anticipated in 2008. The National Academies of Sciences Institute of Medicine will review the evidence white papers to validate that the evidence is adequately and completely described.

As new evidence is gathered, the Evidence Book will be updated. If new evidence indicates that a risk should be retired or that a new risk should be added, the HRP will, after thorough review take the appropriate action to modify the PRD and update the Evidence Book accordingly.

1.4 THE INTEGRATED RESEARCH PLAN

The IRP documents WHAT activities are necessary to fill knowledge gaps, WHEN those activities will be accomplished, WHERE they will be accomplished (e.g. use the International Space Station, use a ground analog), WHO will accomplish them (which project or organization within the HRP), and WHAT is being produced.

1.4.1 Priority

The research plan laid out in this document has been arranged in risk priority order. This priority was assigned by program management to achieve a consistency with definitions and qualitative criteria.

This approach has the advantage of illustrating the critical risks first and gives the sense of how the research program is focused.

This organization also brings with it a feature that detracts from this sense of focus. Each risk has been previously analyzed to expose gaps in knowledge that need to be better understood. When a risk is prioritized at a certain level, at least one of the gaps is prioritized at that level However not all of the gaps for a particular might share that priority. A risk may have gaps that are lower priority than the overall risk priority level. Future versions of the IRP will be prioritized at the gap and/or activity level.

Criticality of a risk for Lunar or Mars mission alone is not sufficient to determine the optimum level of activity (or budget) or timing of research investments. Many other factors combine to determine the critical path: limited availability of certain critical resources like the Space Shuttle and the ISS, or the exceptionally long lead times needed improve understanding and mitigation of radiation risks. All of the factors needed to determine the critical path are not explicitly represented in the IRP, only the resultant research plan.

For example, the retirement of the Space Shuttle will introduce significant logistics constraints to and from the International Space Station (ISS). The ISS has resource limitations such as crew-time, imposing a strong planning constraint on research involving human interaction, or the human as a subject. Given this environment, these complex constraints affect the research planning. Conversely a well developed research plan assures that research that requires space flight conditions are clearly prioritized to optimize the use of the platforms.

Three categories of prioritization have been developed for the risks: 1) Desirable; 2) Important, and 3) Critical. Each of these categories is applied to two different mission scenarios, the Lunar mission(s) (including the Lunar outpost missions) and the Mars mission.

For reference, each risk heading in this document is labeled with an abbreviated version of the Lunar X Mars priority.

Criteria for prioritization of the risks applicable to the Lunar mission(s) are:

- **Desirable** to Quantify and Reduce Prior to the Lunar Mission: The absence of data or risk mitigation countermeasures in this area (beyond what is available at the baseline date of this document) would not delay the Lunar mission even if all other elements of the mission were ready (e.g., if the launch systems, EVA systems, landing and life support systems were ready), but quantifying and reducing the risk would reduce the risk for that particular discipline. Engineering or operational workarounds/constraints could be avoided if this risk were quantified and/or reduced.
- Important to Quantify and Reduce Prior to the Lunar Mission. The absence of additional data or risk mitigation countermeasures in this area (beyond what is available at the baseline date of this document) would likely not delay Lunar Mission even if all other elements of the mission were ready (e.g., if the launch systems, EVA

systems, landing and life support systems were ready), but would leave the mission with significant residual or unknown risk. Mission Loss or major impact to postmission crew health could occur if this risk is not quantified and reduced.

• Critical to Quantify and Reduce Prior to the Lunar Mission. The absence of additional data or risk mitigation countermeasures in this area (beyond what is available at the baseline date of this document) would likely delay Lunar Mission even if all other elements of the mission were ready (e.g., if the launch systems, EVA systems, landing and life support systems were ready). The lack of this data or an adequate additional mitigation would leave NASA with unacceptable uncertainty in the residual risk, and/or with unacceptable absolute risk to human health and performance, thus precluding NASA's ability to embark on the mission.

Criteria for prioritization of the risks applicable to the Mars mission(s) are:

- **Desirable** to Quantify and Reduce Prior to the Mars Mission: The absence of data or risk mitigation countermeasures in this area (beyond what is available at the baseline date of this document) would not delay the Mars mission even if all other elements of the mission were ready (e.g., if the launch systems, EVA systems, landing and life support systems were ready), but quantifying and reducing the risk would reduce the risk for that particular discipline. Engineering or operational workarounds/constraints could be avoided if this risk were quantified and/or reduced.
- Important to Quantify and Reduce Prior to the Mars Mission. The absence of additional data or risk mitigation countermeasures in this area (beyond what is available at the baseline date of this document) would likely not delay the Mars Mission even if all other elements of the mission were ready (e.g., if the launch systems, EVA systems, landing and life support systems were ready), but would leave the mission with significant residual or unknown risk. Mission Loss or major impact to post-mission crew health could occur if this risk is not quantified and reduced.
- Critical to Quantify and Reduce Prior to the Mars Mission. The absence of additional data or risk mitigation countermeasures in this area (beyond what is available at the baseline date of this document) would likely delay the Mars Mission even if all other elements of the mission were ready (e.g., if the launch systems, EVA systems, landing and life support systems were ready). The lack of this data or an adequate additional mitigation would leave NASA with unacceptable uncertainty in the residual risk, and/or with unacceptable absolute risk to human health and performance, thus precluding NASA's ability to embark on the mission.

Ultimately, prioritization of the risks, the gaps and the activities can be conducted through a Probabilistic Risk Assessment that integrates and compares the reduction of the overall risk to the mission, given different mission scenarios, research approaches, and outcomes. The HRP will use the RMAT tool to categorize and assess the risks and gaps according to priority. At present though, there is not an integrated or validated PRA tool that will allow the use of the RMAT data to do the cross-comparison or the prioritization of risks or gaps.

Until the availability of such a tool, the HRP relies on expert opinion, with consideration of the existing evidence. The HRP's Science Management Office has the task of prioritizing the HRP's research portfolio as described in the HRP Science Management Plan (HRP-47053) Paragraph 3.1.

1.5 SCHEDULE DRIVERS AND CONTEXT CONSIDERATIONS FOR THE READER

Research is inherently non-linear. The one constant about the IRP is that it will change. As knowledge is gained, our understanding of the required approach changes. This document represents the best plan available at this moment in time. It would be impractical to assume a linear approach with respect to future research plans. The IRP will be revised and updated yearly based on available resources, Constellation and other schedule constraints, and a consideration of new evidence that was gained in the previous year.

The fidelity of the research plan is related to the timeframe for which it is planned. For instance, the fidelity of requirements for the research described in this plan for 2008-2009 is high. On the other hand, the fidelity of requirements for activities listed in this plan beginning in 2020 is lower. The yearly update will allow these descriptions to change as new evidence is considered and key milestones are achieved.

This version (#1) represents the initial definition of an integrated research plan based upon the HRP's current research portfolio. Future versions of the IRP should include a more detailed review of the ties of the knowledge gaps to the evidence base for each risk.

NASA has laid out some very specific schedule milestones for implementation of the Vision for Space Exploration (VSE). The Shuttle retirement in 2010, the Orion vehicle in 2014, and the first Lunar sortie by 2020 together create urgency for the acquisition of knowledge. The use of the Shuttle and ISS platforms, in several cases, is critical to obtaining the required knowledge to build products supporting longer, more challenging missions. In some cases, research is accelerated to take advantage of the availabilities of those vehicles.

This plan is NOT intended to mitigate risks associated with the ISS. The ISS is used as a platform to conduct research aimed at mitigating risks to the exploration missions. Some of the research may identify countermeasures, engineering or operational solutions that would enhance the ISS and reduce risk in use of that platform. In those cases, the HRP identifies the necessary deliverables and insertion points for the ISS. However, the focus of this document is to identify deliverables necessary to complete the exploration (Lunar and Mars) missions.

This plan includes activities that are more than "Research or Technology Development". In some cases, the activities reported in this document are not explicitly "research" or "technology development", but are included to ensure logical completeness in describing those activities necessary to mitigate the risks. Examples are data mining activities, the results of which are pivotal in defining further steps in the research path, and hardware evaluations which would further our engineering approach to mitigating a risk.

Human health and performance risks can best be mitigated through the space system design. The HRP works closely with the Constellation program to communicate the areas of human health and performance risks, and to help advise in the engineering and development of the Constellation systems. Mitigation of many human health and performance risks can be accomplished through engineering design and operational constraints, and do not need further research. Decision points in the research schedules are placed to evaluate whether the engineering design approaches are

adequate, or whether other countermeasures are necessary. As a rule, engineering should be the first method of dealing with these issues; however, much of the research may continue to be necessary to relieve overly burdensome engineering or operational constraints.

A flight resource analysis is necessary. A key next step for this document is to identify the flight resources required to implement the described research and compare those resource requirements with the projected availability. If a shortfall exists, the HRP will work with the ISS program to develop the appropriate approach. If it is found that the HRP complement of research cannot fit into the available flight resources, the prioritization will be used to identify those investigations most critical to facilitate exploration.

Key Decision Points are built into the research plan. At these points the HRP will evaluate data pertaining to likelihood and consequences and perform risk analysis to determine the proper approach. In some cases likelihood with existing countermeasures will not be high enough to warrant proceeding with more research.

2.0 SUMMARY OF THE RESEARCH PLAN (THIS SECTION IS TBD)

The development of this document has been evolutionary. The HRP recognizes that the format of this document, while comprehensive in its scope requires an additional high-level summary to facilitate a quick understanding of the overall research plan. Further, the integration of research across discipline lines has yet to be completed. A future version of this section is intended to provide a high-level summary of the research approach and planning for each risk. It will also describe how the HRP is performing the integration of research activities across risks.

For each risk in this document, a summary paragraph, an outline of the major gaps, and a short description of the research approach to fill the gaps will be given.

Many activities described in this document address multiple gaps. A different and easier way of viewing their applicability will help to understand the integrated nature of the particular research approach. This section will capture the activities that address multiple gaps, describe the general approach, how each of these activities relates temporally to the research planning and how it relates to the relevant risks. Examples of these activities are the post-flight functional task performance test, the 6-degree head-down bedrest testing environment, and the Lunar bedrest environment.

3.0 ELEMENTS INPUT DESCRIPTION

The format for the Elements' inputs will include graphical depiction via Gantt charts and written discourse to clarify the Element position. Each input follows the same form. The Risk is reported, the Operational Relevance is described, the risk priority is given, the gaps in knowledge are reported with a brief description and for each gap, and the activity or activities necessary to address the gap are described. For each activity, the resulting product/deliverable is described and each required delivery milestone for the deliverable is given along with the required platform and Project or organization responsible for implementing the activity.

3.1 RISKS

Each text description has a description of the risk. These descriptions are verbatim from the Program Requirements Document and are reprinted in the IRP as a matter of convenience for the reader.

3.2 CONTEXT OF RISK FOR EXPLORATION

After each risk description is a paragraph entitled Operational Relevance and Risk Context. In this paragraph, a description of the relevance to the exploration mission is given. This section gives the context within which the research plan is built for that risk and describes the need for the research at a very high level.

3.3 PRIORITY

The priority for the risk for each mission is given. This priority uses the criteria described in the section above.

3.4 GAPS

Gaps in our knowledge or evidence base exist for each risk. These gaps have several different forms. A gap may exist in our evidence base, which leaves greater uncertainty regarding the likelihood of the risk. A gap may exist in the identification of the appropriate countermeasure. For others, the gap may be in the flight validation of the appropriate countermeasure. For the purposes of this IRP, the gaps are not delineated by type; rather they are simply identified as a gap that must be filled before the risk is mitigated. In some cases, the gap may not require research to fill it, but rather can be avoided altogether through selection of a specific Constellation design.

3.5 ACTIVITIES

Under each gap are one or more activities required to fill the gap. The activity is named and a short description is given. In some cases an activity can address multiple gaps perhaps across many different risks. To limit the size of this document, an activity that addresses many different gaps is named and described once and the description is referred to in the other gaps that it is intended to fill.

3.6 PRODUCT/DELIVERABLES

Each activity is designed to culminate in a product or deliverable. These deliverables are structured to feed into the Constellation program, the Office of the Chief Health and Medical Officer or the Mission Operations Directorate. Several different types of deliverables exist. An activity can result in recommended updates to the Space Flight Human System Standards. In that case, the HRP forwards the recommendation to the Chief Health and Medical Officer for incorporation into the standards. Some deliverables result as information to a particular operations constraint. The HRP will identify the appropriate Mission Operations organization (Medical Operations, Flight Operations, Ground Operations or the Operations Office) within the Constellation Program to which changes in their operational approach will be recommended. Other deliverables take the form of requirements. In those, the HRP will recommend requirements changes for the

Constellation program documentation. Another deliverable takes the form of countermeasures. These are approaches, whether physical or pharmaceutical, that is used to mitigate the risk.

3.7 REQUIRED DELIVERY MILESTONE

Key milestones within the Constellation Program development drive the required date for the HRP deliverables. For instance, design requirements typically must be defined by the appropriate System Requirements Review. Design solutions and technology typically must be defined to a TRL6 level by the Preliminary Design Review. This section documents the schedule drivers for the delivery milestones.

3.8 REQUIRED PLATFORMS

This section defines the platform required to perform the research. Platforms can be designated as Ground analog environments, such as NEEMO, Antarctica, etc, or the platform may be a space based one, such as STS or the ISS. Also, the Lunar surface is a platform that is anticipated in some research efforts.

3.9 PROJECT OR ORGANIZATION RESPONSIBLE FOR THE IMPLEMENTATION OF ACTIVITY

Within the HRP elements, there are one or many projects chosen to implement the element research plan. The project is identified in this section. In some cases, organizations outside the element are responsible for implementation of the research, such as the NSBRI or even an international partner. These organizations are identified in this section.

This section identifies the project with primary responsibility for implementing the activity. In some cases the project is not within the element responsible for the risk. The element responsible for the risk will coordinate with the appropriate project in those cases.

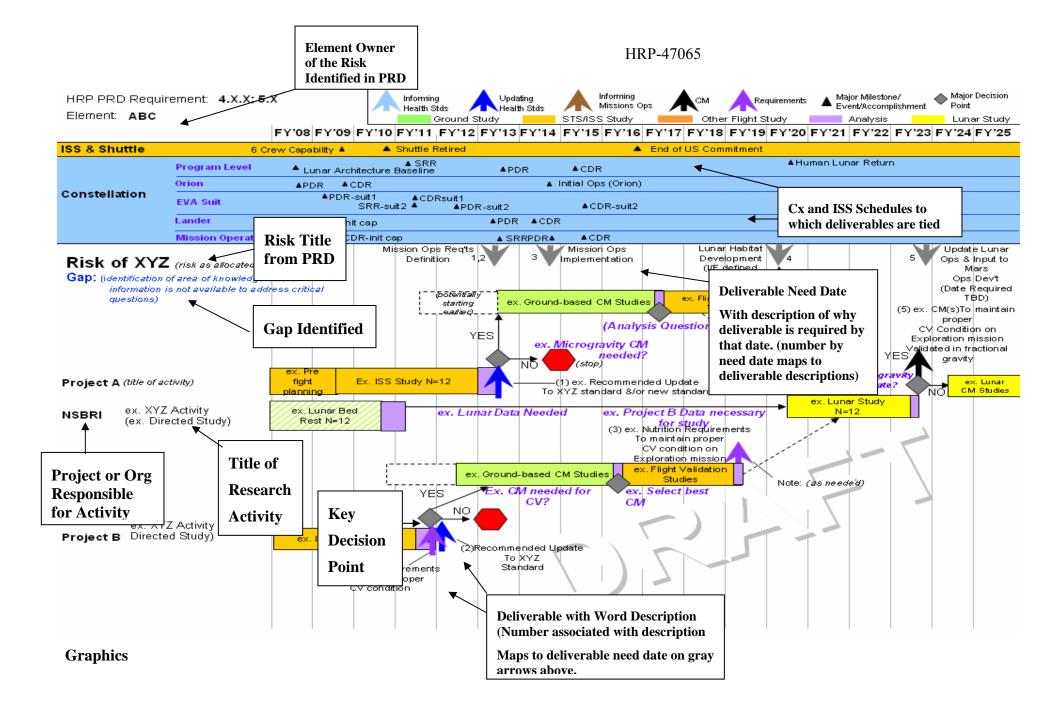
Discipline teams include participation of operations personnel, the NASA research discipline experts, and the NSBRI. In several cases, the primary responsibility is shown as that of NASA, however, that does not mean that the NSBRI is not participating at all. The NSBRI participates through the discipline teams as well as through future solicitations.

3.10 GRAPHIC INPUT

Each graphic is supported with text that provides a more thorough level of detail. Figure 2 shows an example Gantt chart and labels each section of the chart. Each Gantt chart is associated with one of the 33 PRD Risks. The element to which the risk is allocated is identified in the upper left corner. For each risk, the research gaps are identified by name and number along the left side. Under each gap are the identified activities required to fill the gap. Each activity is identified by name and the acronym of the project or organization responsible for implementing the activity. In some cases, the organization responsible for implementing the activity may not be directly controlled by the element responsible for the risk. The schedule of each activity is shown on the graphic and an arrow shows deliverables resulting from the activity. The activities are color coded, gold for STS/ISS activities, green for ground activities, purple for data analysis, and yellow for Lunar activities. Cross-hatched colors represent activities conducted by the NSBRI. Small text identifies each deliverable. A number on each text deliverable description relates the deliverable to the need date, shown by the gray numbered arrows at the top of the chart.

3.11 DECISION POINTS

Several key decision points have been placed in the plan. At these key decision points the appropriate forward path for the research will be reevaluated. The decision points are cast in a "Yes/No" form, and it is anticipated that at these points, the responsible element will review the overall current state of the evidence, and review the appropriate approach to the forward plan. Where applicable, the Science Management Office will concur and, if necessary, the appropriate Project Standing Review Panel may be convened to deliberate and make recommendations. Criteria for making the decision will be determined on a case by case basis and will be consistent with the overall management structure documented in the Science Management Plan. The process will be implemented consistent with the Program Implementation Plan. In many cases, an activity addresses more than one risk.



4.0 RISK OF INABILITY TO ADEQUATELY TREAT AN ILL OR INJURED CREW MEMBER I X C

Mission architecture limits the amount of equipment and procedures that will be available to treat medical problems. Resource allocation and technology development must be performed to ensure that the limited mass, volume, power, and crew training time be efficiently utilized to provide the broadest possible treatment capability. This allocation must also consider that not all medical conditions are treatable, given the limited resources, and some cases may go untreated.

Operational Relevance and Risk Context

NPD 8900.3F - The immediate and long-term responsibilities of NASA with regard to the human space flight program require that the Agency provide medical and dental care, observation, and study to astronauts, payload specialists, and other space flight participants while on active duty with NASA. This care, observation (to include health monitoring), and study will be provided, utilizing the best current guidelines for the clinical practice of medicine and dentistry, and will be comprehensive in scope as applicable to the NASA mission. It will encompass all aspects related to the mission, including certification and training, and will include all space flight mission phases (pre-, in-, and post-flight).

Priority

Lunar Outpost Mission (Level of Care 4): Important to Quantify and Reduce Prior to the Lunar mission.

Mars Mission (Level of Care 5): Critical To Quantify and Reduce Prior to the Mars Mission.

Gaps

ExMC1: Data and Information that make up the NASA medical evidence base used for risk assessment and planning are not all in a form that supports easy access and analysis.

Activity:

Mission Medical Information System

Incorporate medically relevant clinical information into a database system for use in operations as well as for research support. The data sources to be incorporated include MRID as well as other mission data. Currently the data resides on an FTP server, in flight surgeon files, some in the Electronic Medical Record (EMR), and some in the database for the Longitudinal Study of Astronaut Health (LSAH). Structured data sources such as the EMR and LSAH will not be duplicated, but rather joined. Effort is aimed at getting data into structured form first and then work on data entry at the point of collection. Effort is co-funded 50/50 with Crew Health and Safety.

Product/Deliverables:

Structured Information System fully populated with NASA medical space flight data and information.

Required Delivery Milestone:

Operational Mission Medical Information System in FY2013 to meet Orion operations.

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NASA JSC

ExMC2: Planning tool not available that correlates in-flight medical hardware/consumables to medical risks.

Activity:

Integrated Medical Model

Due to limited resource volume constraints of the mission designs (including volume, mass, power, crew time, and crew skills), only the most critical medical equipment will be stored onboard the space vehicles to treat illnesses or injuries. In addition, pre-flight crew training is limited to those medical procedures most likely to occur. Because the astronauts are not likely to be trained medical clinicians, their skill level must be considered in the treatment of medical procedures. The likelihood of critical patient conditions occurring along with the required resources (including those listed above) to treat the conditions must be analyzed to determine the level of risk to the astronauts in a quantitative manner. This allows management tradeoffs between resources and acceptable risk levels for various mission scenarios. The Integrated Medical Model (IMM) is intended to provide this quantitative risk assessment.

Product/Deliverables:

Validated model

Required Delivery Milestone:

First release FY2010 to inform decisions for the Orion medical kit contents

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NASA JSC and GRC

ExMC3: Lack of complete and accessible repository of space flight biomedical data

Activity:

Life Sciences Data Archive

NASA's Life Sciences Data Archive (LSDA) is a work in progress that provides information and data from spaceflight experiments funded by the National Aeronautics and Space Administration (NASA). The archive includes investigations from 1961 (Mercury Project) through current

missions (International Space Station and Shuttle) involving human, plant and animal studies. Effort includes a process to streamline access while protecting confidentiality.

Product/Deliverables:

Archive flight and relevant ground experiments

Retrospective data entry

Required Delivery Milestone:

Ongoing

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NASA JSC and ARC

ExMC4: Improved techniques for crewmember to conduct medical procedures in necessary time

Activity:

Assisted Procedures Techniques

Due to the limited medical skills and training of the crew, techniques to help the crewmembers perform medical procedures will be required. This will reduce the time required to perform the procedure, allow the crew to refresh their training skills during the mission, and provide the crew with audio and visual information to guide them through the procedure efficiently. This may develop into a decision support system.

Product/Deliverables:

"Guideview" software that is compatible with Constellation Personal Data Assistant (PDA) platform that will replace the standard "medical checklist".

Voice recognition technology integration

Required Delivery Milestone:

FY2011 release for Orion use; updates and voice recognition for Lunar missions

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NASA JSC

ExMC5: Improved ability to monitor crewmembers physiological data during a mission

Activity:

Biomedical Sensors

By monitoring crewmembers' physiological data flight surgeons may be able to detect emerging medical problems. During EVAs and periodic IVA activities, the flight surgeons need the ability to monitor key physiological signals that indicate the crew's work load and other physiologic parameters. The current system for donning the sensors is time consuming and inconvenient, requiring shaving, application of electrodes, and signal checks. A more efficient system will save crew time and reduce the overhead of stowing additional supplies. This system will be achieved through the integration of small, easy to use biomedical sensors capable of measuring, storing and transmitting physiologic parameters (ECG, SPO2, heart rate, BP, ETCO2, temp, etc) during operational and ambulatory activities. Such a system could also provide a wealth of data for the medical and research communities. Coordination with the HHC element for an overall medical and research biomedical sensing plan will occur.

Product/Deliverables:

Requirements and up to TRL 6 prototype systems for EVA and IVA sensing.

Required Delivery Milestone:

Requirements for EVA and IVA system SRR's, TRL 6 prototype systems in advance of EVA and IVA system PDRs

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NASA JSC, EPSP ARC and GRC; negotiations with Cx EVA Project ongoing for responsibilities

Activity:

Non-invasive Biosensor Algorithms for Continuous Metabolic Rate Determination

Develop and validate algorithms to accurately calculate VO_2 from NIR spectra collected from muscle; 2. Develop and validate algorithms to simultaneously calculate muscle temperature; 3. Support incorporation of the sensor algorithms into the EVA suit testing for non-invasive continuous metabolic rate assessment during Lunar EVA.

Product/Deliverables:

- 1. New software to measure VO₂ using the NIRS-monitor hardware currently in use at JSC and improved hardware when available 9/30/2011;
- 2. New software to measure muscle temperature using the NIRS-monitor hardware currently in use at JSC and improved hardware when available -3/1/2011;
- 3. Documentation of validation studies performed before, during and after bed rest rest. 9/30/2011;

4. Recommendation for sensor placement sites for use during lunar EVAs to best estimate whole body VO_2 . -9/30/2011.

Required Delivery Milestone:

TRL 6 system for EVA Configuration 2 PDR

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC, EPSP and ARC. Negotiations with Cx EVA Project ongoing for responsibilities.

Activity:

<u>Lightweight</u>, <u>Wearable Metal Rubber-Textile Sensor for In-Situ Lunar Autonomous Health</u> Monitoring (SBIR)

Develop and demonstrate a low-weight, non-invasive, reliable and comfortable autonomous health-monitoring system for use by astronauts during long-duration space missions and extravehicular activities (EVAs).

Product/Deliverables:

<u>Technical Task 1 (Month 0-1)</u>: Define Program Parameters and Plan for Materials

Synthesis.

<u>Technical Task 2 (Month 1-3)</u>: Fabricate Nanocluster Precursor Materials for Self-Assembly of Metal RubberTM Textile Sensors / Interconnects.

<u>Technical Task 3 (Month 3-6)</u>: Construct Health Monitoring Shirt Demo using Metal RubberTM Sensors and Interconnects.

<u>Technical Task 4 (Month 6-10)</u>: Fully Characterize the Ability for the Metal RubberTM Textile Shirt to Monitor Physiological Parameters, such as EKG, Heart Rate, and Body Core Temperature.

<u>Technical Task 5 (8-12)</u>: Design and Develop a Wearable Data Acquisition / Sensor Response Storage System for Physiological Data.

<u>Technical Task 6 (Month 12-16)</u>: Based on Characterization and Input from NASA COTR and Commercial Collaborators, Improve Sensor Shirt Design and Reconstruct with Data Capture Component.

<u>Technical Task 7 (Month 15-18)</u>: Fully Characterize the Improved MR[™] Smart Shirt Similar to Task 4 and Compare Performance.

<u>Technical Task 8 (Month 15-20)</u>: Analyze the MR[™] Smart Shirt Performance to NASA Space Based Standards and Relevant FDA Standards.

<u>Technical Task 9 (Month 20-24)</u>: Increase Manufacturability and TRL Level.

Technical Task 10 (Month 22-24): Work with NASA and LM-MS2 to Implement Phase III

Required Delivery Milestone:

End of 2-year funding period

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

SBIR, NASA JSC, EPSP and ARC.

Activity:

Wearable Health Monitoring Systems (TBR-1 SBIR)

To build a working prototype of the wearable health monitoring system that will demonstrate: 1) the integration of medical sensors, electrodes, electrical connections, circuits, and power supply into a single wearable assembly to simplify donning and doffing, 2) the distribution of electrical circuits around the human torso to reduce bulk and enable it to be worn underneath an LCVG, 3) the facility to easily replace electrodes attached to the skin, 4) the ability to measure biological sensor data and transmit it to an external computing device, and 5) the simplicity of adding medical sensors to the system through use of a digital data-bus to reduce overall wiring count.

Product/Deliverables:

- Part 1. Design and physical construction of a wearable health monitor for the purposes of initial testing.
- Part 2. Design and coding of a software system for operating the wearable health monitor.
- Part 3. Rigorous testing of the wearable health monitor system.
- Part 4. Design and testing of specific medical sensors integrated within the wearable health system.

Required Delivery Milestone:

End of 2-year funding period.

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

SBIR, NASA JSC, EPSP and ARC.

ExMC6: Lack of options for providing waste management and pharmaceutical delivery for the contingency scenario of a crewmember being in their EVA suit for up to 144 hours.

Activity:

Advanced Medical Fluids

Research and development of technologies for integration into the EVA suit architecture to manage fluids in a contingency requiring extended stays in the suit.

Product/Deliverables:

Improved Maximum Absorbency Garment (MAG) for waste management

Vacuum-rated injectable medications

Required Delivery Milestone:

MAG: FY2012 – TRL6 for Cx EVA Suit 2 PDR

Vacuum-rated injectables: FY2011 – TRL6 for Orion Medical Kit PDR

Required Platforms:

Possible use of the ISS for validation of fluid systems that can't be validated in reduced gravity aircraft.

Project/Organization Responsible for Implementation of Activity:

NASA GRC, EPSP

ExMC7: Inability to analyze biological samples during exploration missions with minimum consumables.

Activity:

Lander/Outpost Inflight Lab Analysis

Analyzing body fluids (urine, blood, saliva) on the lunar surface will reduce launch/return mass/volume and provide the data near real-time. A system to perform this analysis inflight is necessary to meet these requirements. NASA has conducted several trade studies analyzing hardware available and developed an Excel-based tool to quantify the ability of hardware to meet mission requirements. To reduce system mass and volume, beginning with the FY 2007 SBIR call and the FY2008 budget year, NASA will begin developing concepts and hardware for reusable systems of this type.

Such miniaturized systems are dependent upon space medical standards and requirements. These standards and requirements are critical for engineering and medically qualifying the appropriate system for remote space applications. The results of the recent Sample Return Analysis task may be considered in the near-term for potential ExMC leveraging opportunities. In addition to microfluidic processing systems, non-invasive monitoring devices may be considered.

Product/Deliverables:

TRL 6 system for lunar lander and outpost medical system PDR's.

Required Delivery Milestone:

TRL6 unit available in FY2015 to support Lunar missions

Required Platforms:

Require the ISS for, micro-g validation in an operational environment.

Project/Organization Responsible for Implementation of Activity:

NASA ARC and GRC

Activity:

Handheld Body-Fluid Analysis System for Astronaut Health Monitoring

Development and demonstration of an automated handheld blood count instrument that is capable to perform white blood cell count on a nanoliter sized blood sample using MEMS technology and is easy to operate. The system should analyze a minimum of 1,000 RBCs and 200 WBCs which corresponds to processing sample volume ~50-100 nL of whole blood. Ability to provide both blood count and differential will be demonstrated.

Product/Deliverables:

A monolithic chip will be developed to perform the measurement of red blood cell (RBC) count, mean cell volume (MCV), hematocrit, white blood cell (WBC) count and at least a 2-part differential (lymphocytes versus granulocytes).

Required Delivery Milestone:

End of funding period

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC and ARC

Activity:

<u>Development of a Modular, Fiber Optic Surface Plasmon Resonance Sensor for Quantitation of Diagnostic Proteins for Healing of Burns and Wounds</u>

Development of a fiber optic system utilizing surface plasmon resonance for detection of clinically relevant levels of diagnostic proteins

Product/Deliverables:

Modular fiber optic sensor platform capable of measuring multiple analytes for assessment of biomarker detection

Required Delivery Milestone:

End of funding period

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC and ARC.

ExMC8: Lack of Advanced Medical Life Support Equipment to Treat a Crewmember

Activity:

Lightweight Trauma Module

Onboard advanced medical life support hardware will be required to treat the crewmembers on an emergency basis. Technologies which are smaller, lighter, reliable, and user-friendly will be

required to fit within the limited space of the spacecraft vehicles. Currently on the ISS, the crewmember's source of additional oxygen if needed is the onboard oxygen tanks. The system provides 100% oxygen to the crewmember continuously, exceeding the spacecraft oxygen limit within minutes. For the smaller Constellation vehicles, close interface with spacecraft designers and fire safety experts will be required to ensure safety margins are met. A system which concentrates the oxygen within the cabin environment and provides the required concentration of oxygen to the crewmember based on their oxygen saturation level will be necessary to meet these requirements.

Product/Deliverables:

TRL 6 model for Lunar missions, coordination with the military

Required Delivery Milestone:

Lunar surface model, TRL6 ready in FY2015

Required Platforms:

Ground

ISS flight model will be developed as part of the Health Maintenance System upgrade

Project/Organization Responsible for Implementation of Activity:

NASA JSC

Activity:

<u>Determination of Oxygen Requirements in Hypoxic Environments</u>

To determine oxygen requirements during the first week of hospitalized patients with illness and or injury most likely to occur in spaceflight

To define oxygen requirements and risk of hypoxemia of critically ill/injured warfighters requiring mechanical ventilation and transport in a hypobaric/hypoxic environments

Product/Deliverables:

Research demonstrating the actual oxygen requirements for crewmembers requiring ventilation

Market research on current O2 concentrators and their specifications

Required Delivery Milestone:

End of funding period

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC

Activity:

Guided High Intensity Focused Ultrasound (HIFU) for Mission-Critical Care (TBR-2 NSBRI)

Develop engineering prototypes of an image-guided HIFU device that would demonstrate the (separate) capability of inducting acoustic hemostasis (in vivo), tumor ablation (in vivo), and stone comminution (in vitro) (by end of currently funded project; i.e., 7/31/08). Develop an engineering prototype that would demonstrate in a porcine model the capability of detecting and inducing acoustic hemostasis, tumor ablation, and stone comminution in a single, integrated, image-guided, HIFU device (by end of project renewal; i.e., 7/31/12).

Product/Deliverables:

Engineering prototypes of an image-guided HIFU device that would demonstrate the (separate) capability of inducting acoustic hemostasis (in vivo), tumor ablation (in vivo), and stone comminution (in vitro) (by end of currently funded project; i.e., 7/31/08). An engineering prototype that would demonstrate in a porcine model the capability of detecting and inducing acoustic hemostasis, tumor ablation, and stone comminution in a single, integrated, imageguided, HIFU device (by end of project renewal; i.e., 7/31/12).

Required Delivery Milestone:

Technical report of progress toward project goals—7/31/08

Engineering prototypes (by end of project renewal; i.e., 7/31/12)

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC

ExMC9: Inadequate IV Fluids to Treat Emergency Medical Conditions

Activity:

Mixed Water Generation & IV Drug Mixing

Currently, limited quantities of IV fluid are launched, stowed, and disposed of (or returned to Earth due to limited life) on the International Space Station. These IV fluids take up valuable launch mass/volume, stowage volume onboard the ISS, and waste disposal volume. The ability to generate Water for Injection on-demand will minimize these resource impacts. The Water for Injection will be mixed with the necessary medications during the mission for immediate use.

Product/Deliverables:

DTO model for ISS test

FDA approval

Required Delivery Milestone:

ISS model ready for flight in FY2010

Required Platforms:

ISS DTO model required for validation

Project/Organization Responsible for Implementation of Activity:

NASA JSC, ISSMP and GRC

ExMC10: Lack of Advanced Diagnostic Imaging Capability for Exploration

Activity:

Ultrasound/Braslet

This project will enable further understanding of steady-state space cardiovascular physiology in long-duration space flight. This investigation will develop and validate appropriate methodology for studying cardiovascular responses to disturbances (for example, gravity change, volume overload, hemorrhage and others) using existing ISS resources. Future use of this methodology will yield valuable physiological and operational data for planning and support of missions to the moon and other remote destinations.

Product/Deliverables:

Flight certification and support for ISSMC flight.

Required Delivery Milestone:

Data for Space Medicine to decide whether or not to pursue Braslet as a countermeasure

Required Platforms:

ISS

Project/Organization Responsible for Implementation of Activity:

NASA JSC and IBMP

Activity:

A Scanning Confocal Acoustic Diagnostic System for Non-Invasively Assessing Bone Quality

The objectives of this study are to further develop a unique scanning confocal acoustic diagnostic (SCAD) system for bone quality assessment. This system will provide improved resolution, faster scan times (< 5 min for the scan), portability, and the ability to scan multiple sites of the skeleton. In addition, this project will validate image-based characterization of bone's physical properties to true bone quality as based on material testing. This next phase of research will focus on developing the SCAD prototype as a real-time, high-resolution and portable bone-imaging modality for determining bone quality and prediction of fracture risk. Measuring bone structural and strength properties in the cadaver samples, using SCAD, microCT and mechanical testing for bone quality prediction will be performed. Clinical diagnostic assessment will include comparison of SCAD and DXA in osteoporosis and disuse subjects.

Product/Deliverables:

SCAD prototype as a real-time, high-resolution and portable bone-imaging modality for determining bone quality and prediction of fracture risk

Required Delivery Milestone:

Technical report of progress toward project goals — 10/31/08. Small, portable device that uses ultrasound, not X-rays, to determine bone density and quality

Required Platforms:

Ground

Bed rest study

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC

Activity:

<u>Ground-Based Measurement of Bone Loss in Astronauts Using Advanced Multiple Projection Dual Energy X-ray Absorptiometry (AMPDXA) Ground-Based Clinical System</u>

To produce an operational instrument that can be transferred to the NASA-Johnson Space Center for use in the pre- and postflight bone mineral density (BMD) and bone structure measurements on astronauts.

Product/Deliverables:

Device to measure bone density and quality using lower X-ray exposure than current devices. Size and power requirements optimized for space use.

Required Delivery Milestone:

End of funding period

Required Platforms:

Ground based

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC

Activity:

Prototype Testing for Non-Invasive Determination of Intracranial Pressure (ICP) (TBR-3 NSBRI)

Development of non-invasive intracranial monitoring methodology and nn-invasive monitoring of cerebral blood flow using ultrasound.

Product/Deliverables:

Useful nICP model by end of year three that will be finalized in year four

Required Delivery Milestone:

End of funding period

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC

Activity:

Improved Bubble Detection for EVA (TBR-4 NSBRI)

To improve EVA efficiency and safety by developing and validating new bubble detection technology using dual-frequency ultrasound. To create dual-frequency instrument (CDFI) that can detect and size bubbles through the chest wall as they move through the heart. Also, signals consistent with bubbles can be detected in tissue. Potentially, this technology could be used to: (a) characterize bubble dynamics during decompression sickness (DCS), (b) detect the earliest stages of DCS, (c) develop and evaluate non-compressive countermeasures for DCS, (d) diagnose DCS in tissue or joints, and (e) mitigate DCS risk by improving preventive strategies such as oxygen prebreathing and limiting activity at particular times. Developing improved techniques to evaluate DCS countermeasures like oxygen prebreathe.

Product/Deliverables:

Dual-frequency instrument (CDFI) that can detect and size bubbles

Required Delivery Milestone:

End of funding period

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC

Activity:

Intuitive Ultrasound Catalog Grant for Autonomous Medical Care

Develop an intuitive ultrasound image cataloging system which incorporates ground acquired ultrasound whole body images. The catalog will acquire ground-based crewmember images to use for medical diagnosis in space.

Develop a mathematical coupling model based on existing ground/in-flight ultrasound data which will allow microgravity associated morphometric and topographic changes to be predicted. Assess the ability of non-physician crew medical officers (CMO) to acquire and interpret complex ultrasound examinations autonomously or with remote guidance.

Product/Deliverables:

Ultrasound Image Catalog coupled with just-in-time training methods 12/31/11

Required Delivery Milestone:

2011

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

NSBRI, NASA JSC

ExMC11: Lack of Terrestrial Testbed for Lunar/Mars Transits

Activity:

ISS Flight Tests

As medical technology developments mature, the ISS will be used as a validation step for critical items necessary for transits to/from the Moon or Mars.

Product/Deliverables:

TRL 7-8 Protoflight units for ISS test of designs for medical hardware that will be needed in Lunar or Mars transits.

Required Delivery Milestone:

TBD

Required Platforms:

ISS

Project/Organization Responsible for Implementation of Activity:

NASA JSC

Activity:

In-flight Flow Cytometer Project

Product/Deliverables:

In-flight flow cytometer capable of various immunology/hematology support

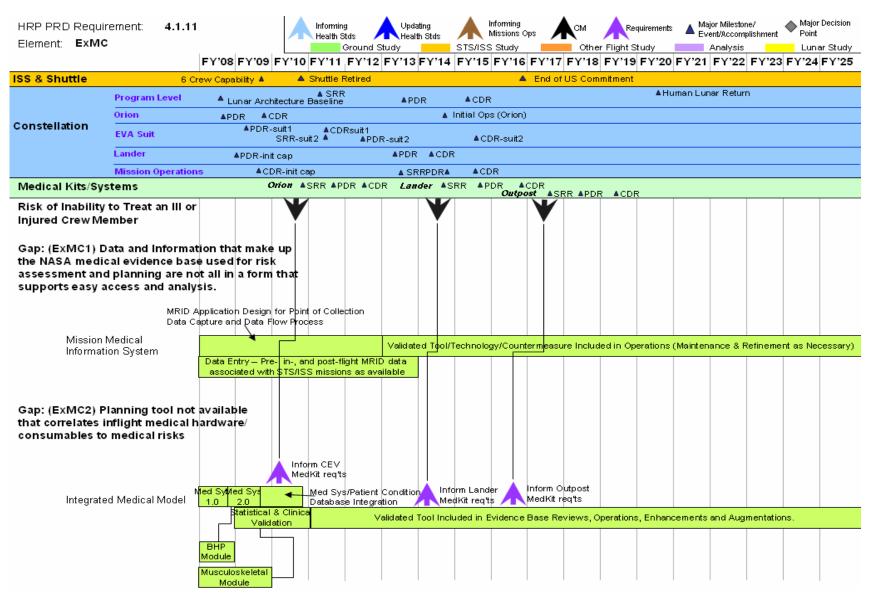
Required Delivery Milestone:

Required Platforms:

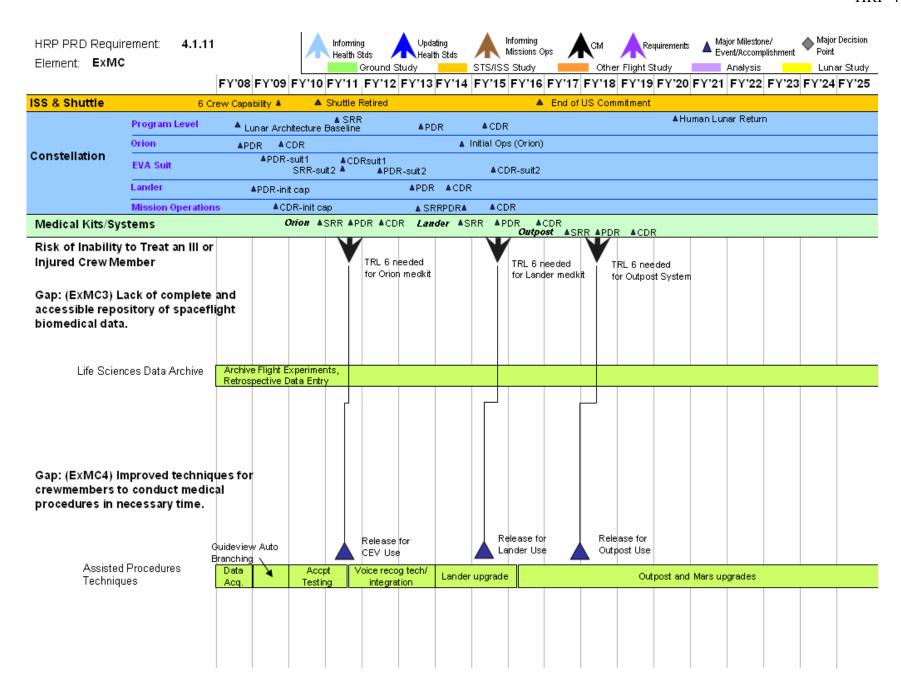
STS, ISS, ground analog

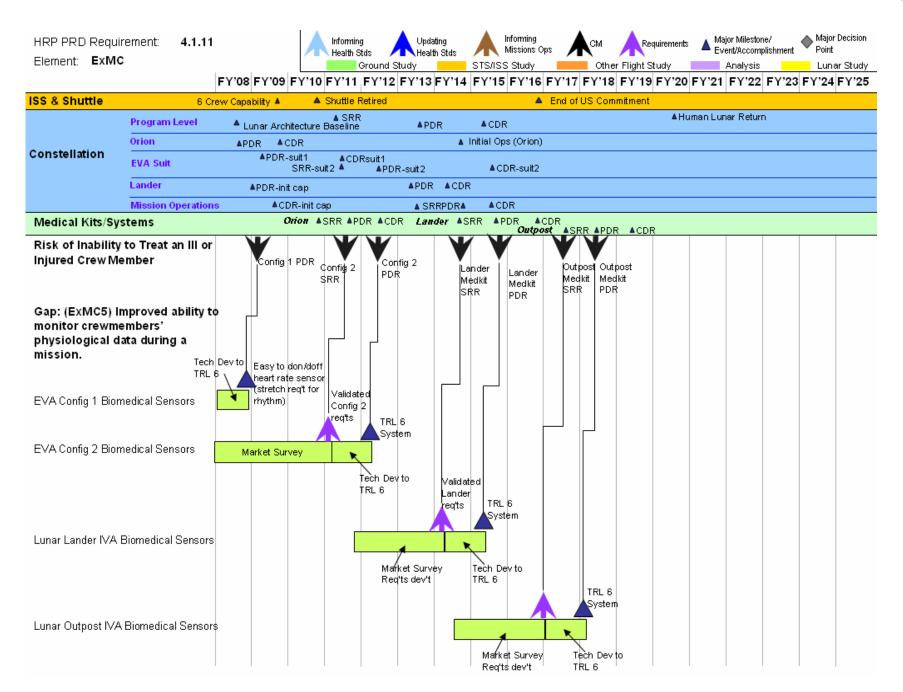
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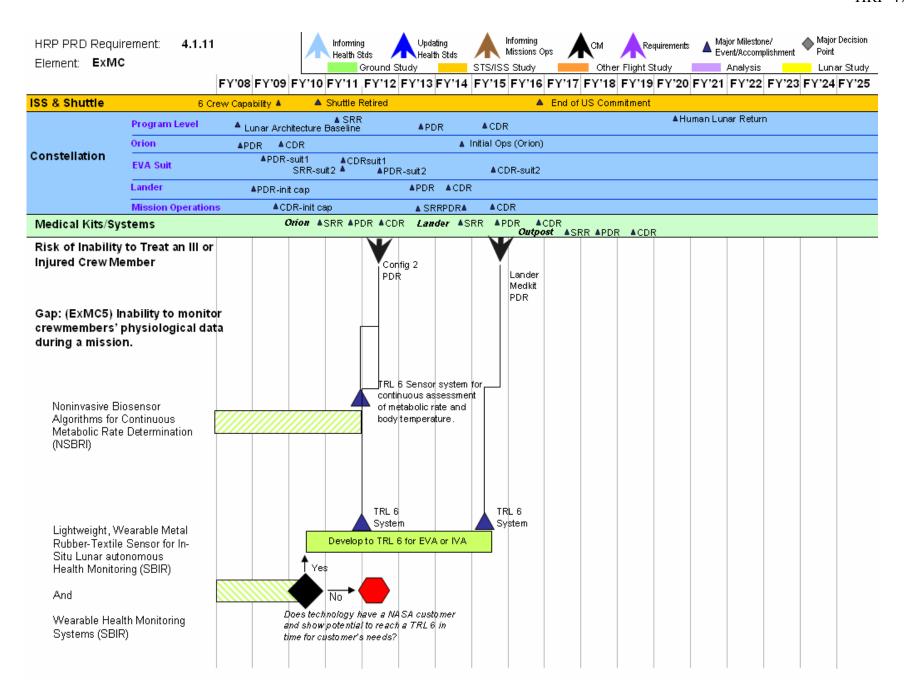
International Space Station Medical Project (ISSMP)

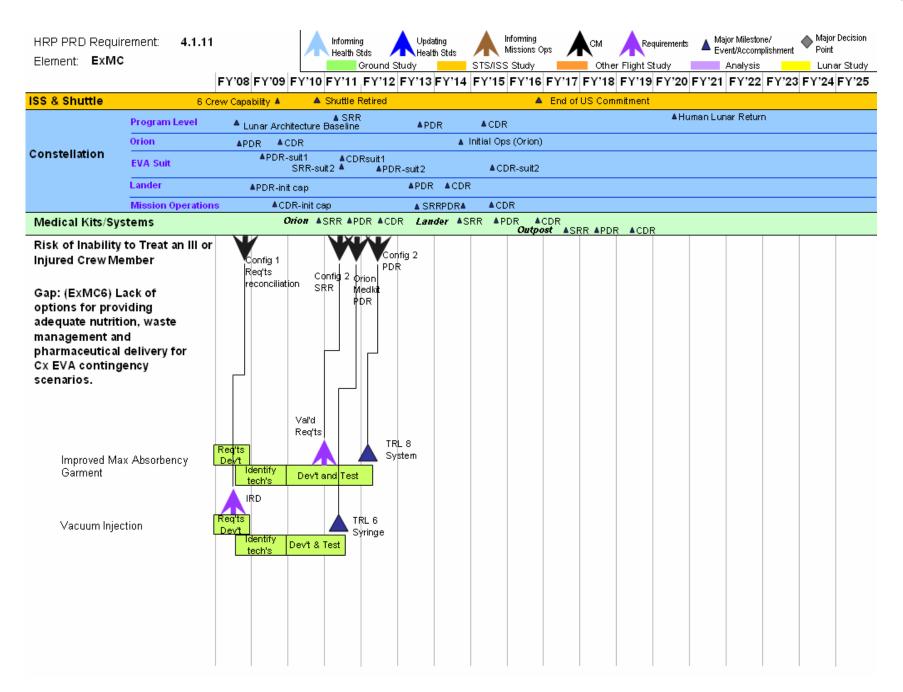


Graphics









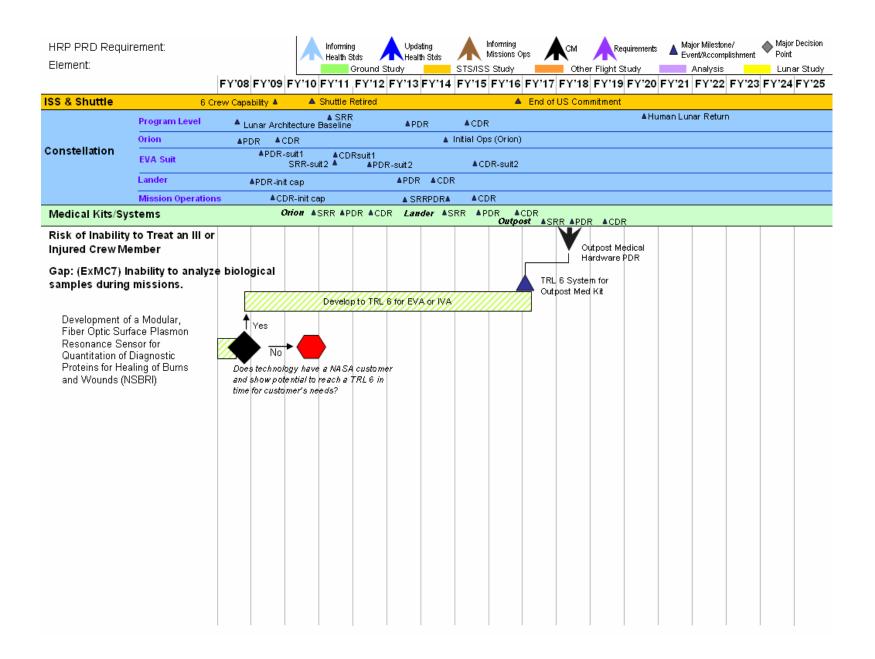
Major Decision Informing HRP PRD Requirement: 4.1.11 Informing Updating Requirements Missions Ops Event/Accomplishment Health Stds Health Stds Element: ExMC Ground Study STS/ISS Study Other Flight Study Analysis Lunar Study FY'08|FY'09|FY'10|FY'11|FY'12|FY'13|FY'14|FY'15|FY'16|FY'17|FY'18|FY'19|FY'20|FY'21|FY'22|FY'23|FY'24|FY'25 ISS & Shuttle 6 Crew Capability A ▲ Shuttle Retired End of US Commitment ▲ SRR Lunar Architecture Baseline ▲ Human Lunar Return **Program Level △**PDR **△**CDR Orion ▲ Initial Ops (Orion) **△**PDR ▲CDR Constellation ▲PDR-suit1 ACDRsuit1 **EVA Suit** SRR-suit2 A ▲PDR-suit2 ▲CDR-suit2 Lander APDR ACDR ▲PDR-init cap ▲CDR-init cap **Mission Operations ∆** SRRPDR**△ △**CDR Orion ▲SRR ▲PDR ▲CDR Lander ▲SRR ▲PDR ▲CDR
Outpost ▲SRR ▲PDR ▲CDR Medical Kits/Systems Risk of Inability to Treat an III or Outpost Medical Injured Crew Member Lander Medical I Hardware PDR Hardward PDR Gap: (ExMC7) Inability to analyze biological samples during exploration missions with Market Survey minimum consumables. Downselect Analogs Tech Integration Regits Def Deliver TRL 6 Testing 8 Prototype System Lander Inflight Lab Analysis Market Survey Analogs Tech Integration Regits Def Deliver TRL 6 Downselect Testing & Prototype System Outpost Inflight Lab Analysis TRL 6 System for Lander Med Kit Develop to TRL 6 for EVA or IVA Yes Handheld Body-Fluid Analysis System for Astronaut Health Monitoring (NSBRI) (Blood

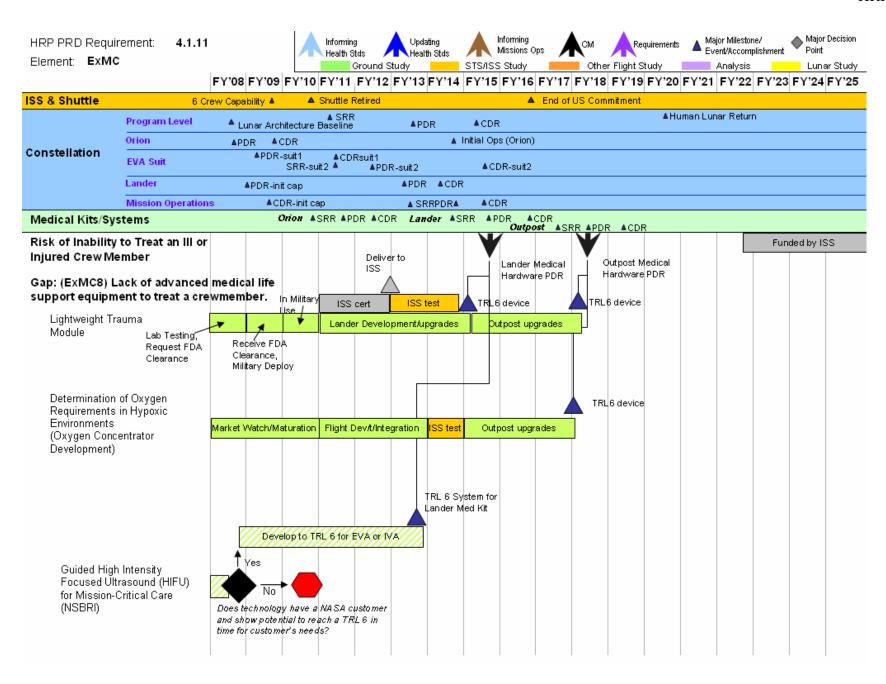
Does technology have a NASA customer

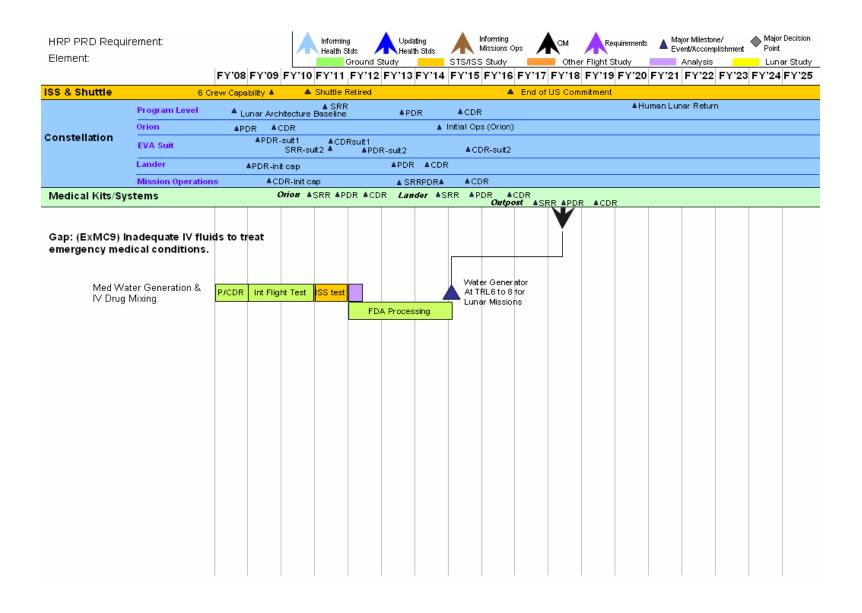
and show potential to reach a TRL 6 in

time for customer's needs?

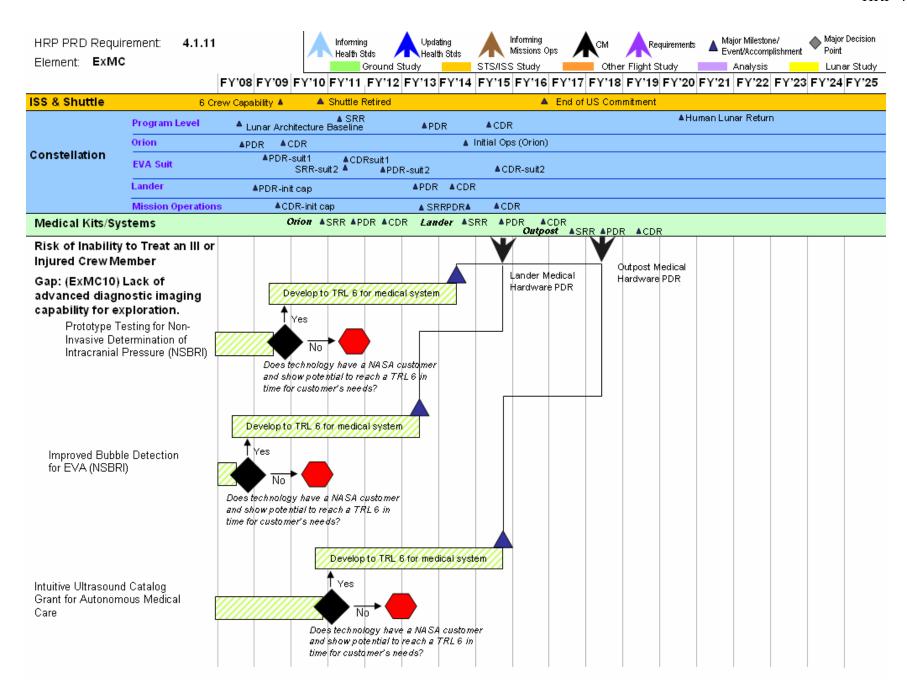
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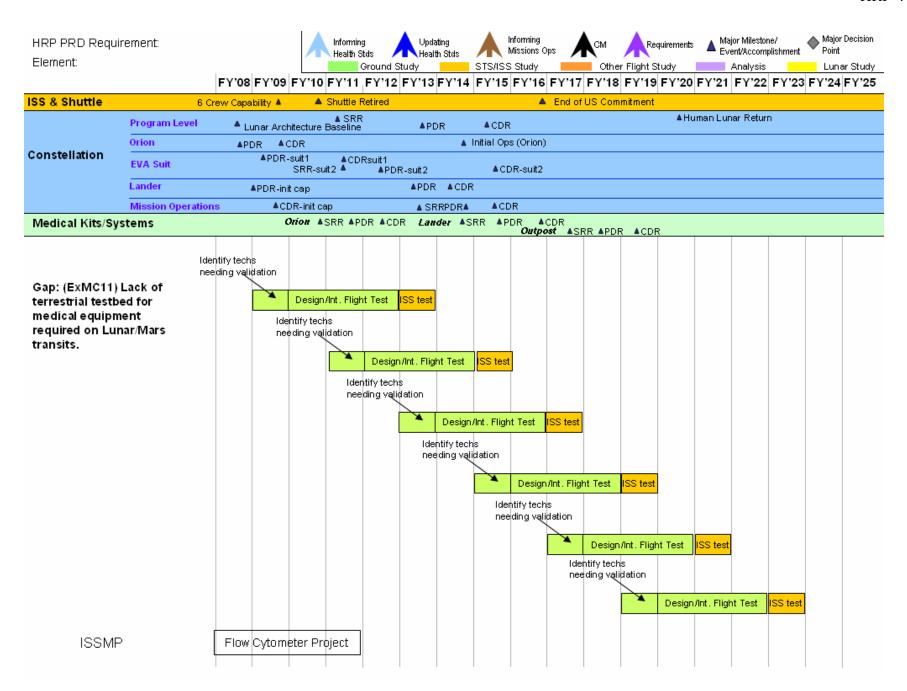






📤 Major Decision Informing Major Milestone/ HRP PRD Requirement: 4.1.11 Updating Informing Requirements Missions Ops Event/Accomplishment Health Stds Health Stds Element: ExMC Ground Study STS/ISS Study Other Flight Study Analysis Lunar Study FY'08|FY'09|FY'10|FY'11|FY'12|FY'13|FY'14|FY'15|FY'16|FY'17|FY'18|FY'19|FY'20|FY'21|FY'22|FY'23|FY'24|FY'25 ISS & Shuttle ▲ Shuttle Retired End of US Commitment 6 Crew Capability A ▲ Lunar Architecture Baseline ▲ Human Lunar Return **Program Level △**PDR **△**CDR Orion ▲ Initial Ops (Orion) APDR ▲CDR Constellation ▲PDR-suit1 **△**CDRsuit1 **EVA Suit** SRR-suit2 A ▲CDR-suit2 ▲PDR-suit2 Lander APDR ACDR ▲PDR-init cap Mission Operations ▲CDR-init cap **∆** SRRPDR**△ △**CDR Orion ▲SRR ▲PDR ▲CDR Lander ▲SRR ▲PDR ▲CDR
Outpost ▲SRR ▲PDR ▲CDR Medical Kits/Systems Risk of Inability to Treat an III or Injured Crew Member Gap: (ExMC10) Lack of Give to SD advanced diagnostic imaging Yes capability for exploration. Ultrasound/Braslet SS test, 5 subits Νo Should Braslet become a medical requirement? Develop to TRL 6 for ground or inflight Yes A Scanning Confocal Acoustic Bedrest Diagnostic System for Non-Study Invasively Assessing Bone Quality (NSBRI) Does technology have a NASA customer and show potential to reach a TRL 6 in time for customer's needs? Develop to TRL 6 for ground evaluations Ground-Based Measurement Yes of Bone Loss in Astronauts Using AMPDXA Ground-Based Clinical System Does technology have a NASA customer (NSBRI) and show potential to reach a TRL 6 in time for customer's needs?





5.0 RISK FACTOR OF INADEQUATE NUTRITION -D X C

It is critical that crewmembers be adequately nourished before and during missions. Critical research areas within this risk include: validation of the correct nutritional needs; assessment of the stability of nutrients during long-duration flight; correct packaging and preservation techniques; effects of countermeasures on nutrition; and use of nutrients as countermeasures.

Operational Relevance and Risk Context

As mission duration increases, the risk of nutrient deficiencies becomes greater. Nutritional countermeasures can influence all systems.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar Mission

Mars Mission: Critical to Quantify and Reduce Prior to the Mars Mission

Gaps

N1: Are nutrients in food stable during space flight?

Activity:

Stability of Pharmacotherapeutic and Nutritional Compounds: Stability SMO (Flight)

See Risk of Inadequate Food System – Gap AFT2

Activity:

Assessment of Nutrient Stability in Space Using Ground-based Simulation of Spacecraft Environmental Factors: Stability SMO (Ground)

See Risk of Inadequate Food System – Gap AFT2

Activity:

Thermostabilized shelf-life

See Risk of Inadequate Food System – Gap AFT2.

Activity:

Advanced Packaging Material Development

See Risk of Inadequate Food System – Gap AFT5.

N2: What is the optimal dose of vitamin D supplementation?

Activity:

Vitamin D Status in an Antarctic Ground Analog of Space Flight

This task will support a vitamin D supplementation study which will evaluate efficacy in this model. Ultimately, the findings will provide long-duration space flight crewmembers with evidence-based vitamin D supplement recommendations for optimal vitamin D status before, during, and after flight.

Product/Deliverables:

Initial product is ground-based study to determine optimal vitamin D dosing.

Required Delivery Milestone:

Study completion and final report of findings in 2009; delivery of improved countermeasure to medical operations in 2009.

Required Platforms:

Ground-based models with limited sunlight exposure are necessary for evaluating vitamin D supplementation efficacy. One such model is subjects spending the winter in Antarctica, where UV-B radiation levels are zero during the winter.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

Activity:

Nutrition Status Assessment – SMO O16E: Nutrition SMO

See Risk of Accelerated Osteoporosis – Gap N7 for details.

This is a directed study that seeks to expand the Medical Requirement 016L testing in three ways: 1) in-flight blood and urine collection and analysis, 2) expand nominal testing to include normative markers of nutritional assessment, and 3) add an R+30 session to allow evaluation of post-flight nutrition and implications for rehabilitation. Additional markers of bone metabolism (helical peptide, OPG, RANKL, IGF-1) will be measured to better monitor bone health and countermeasure efficacy. New markers of oxidative damage will be measured (8-iso-prostaglandin F2a, protein carbonyls, oxidized and reduced glutathione) to better assess the type of oxidative insults during spaceflight. The array of nutritional assessment parameters will be expanded to include serum folate, plasma pyridoxal 5'-phosphate, and homocysteine to better understand changes in folate, vitamin B6 status, and related cardiovascular risk factors during and after flight. Additionally, stress hormones and hormones that affect bone and muscle metabolism will be also measured (DHEA, DHEA-S, cortisol, testosterone, estradiol). This additional assessment would allow for better health monitoring, and allow for more accurate recommendations to be made for crew rehabilitation. These additional parameters were added due to the recommendation of an extramural panel that met to define nutritional standards and requirements in 2005. If data indicate countermeasures are necessary for cardiovascular issues and/or bone loss, additional ground-based studies will be initiated. These countermeasures will be validated on board the ISS.

Product/Deliverables:

The SFHSS nutrition standard will be validated/updated

Required Delivery Milestone:

The SFHSS nutrition standard will be validated/updated in 2011 and again in 2018.

Required Platforms:

ISS is required to ensure that the data represents space normal and for validation of potential countermeasures. The bed rest ground analog (6° head down tilt) is required for ground studies for countermeasure development.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

Activity:

Nutrition Status Assessment – SMO O16E: Nutrition SMO

See Risk of Accelerated Osteoporosis – Gap N7 for details.

N3: How do nutritional status/nutrition requirements change during space flight?

Activity:

Nutrition Status Assessment – SMO O16E: Nutrition SMO

See Risk of Accelerated Osteoporosis – Gap N7 for details.

N6: What impact does flight have on oxidative damage?

N15: Can nutrition/nutrients mitigate O2/radiation risks?

Activity:

NEEMO Rapid Operational Investigation (ROI) study: Characterization of Oxidative Damage during a 12-day Saturation Dive

Oxidative damage resulting from radiation and or oxygen exposure (e.g., during EVAs) is a concern for space travelers. The underwater analog, NEEMO, is a valuable ground-based model for space flight in terms of oxidative damage and changes in iron metabolism. In six (6) subjects from NEEMO5, there was evidence of oxidative damage similar to what is observed during long-duration space flight. In this study, the main objective is to confirm and extend the physiological systems that were affected during the previous NEEMO study. Oxidative damage will be assessed before, during, and after the 12-day mission in the NEEMO habitat. As a result of this study, we will have a better understanding of the type of oxidative damage that occurs in an elevated oxygen environment, and the data can be used to better design countermeasures against this type of damage.

Product/Deliverables:

Initial product is completion of NEEMO study and final report of findings. Study results will be combined with other ground studies (i.e. to-be-solicited cataract study) to determine if a countermeasure is needed against oxidative damage from an elevated oxygen environment. If a countermeasure is needed, ground-based studies will be solicited, followed by flight validation studies.

Required Delivery Milestone:

Study and final report completed by 2009; if countermeasure is needed, ground-based studies solicited and performed 2013-2016. Mission operations will be informed on countermeasure delivery by 2020.

Required Platforms:

Ground-based studies, NEEMO underwater analog facility, ISS required to validate any needed countermeasures.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

Activity:

Cataract Study – TBD

Current 2007 NRA solicitation (NNJ07ZSA002N) requesting research to understand, quantify and prevent oxidative damage resulting from the environment of space and to arrest the effects of elevated oxygen environments necessary for operational activities routinely performed during flight, EVA and surface operations. Analytical methods should include specific cellular and/or blood markers that may be assessed during flight to monitor oxidative damage potential as well as measures to arrest progression of disease states known to be associated with high oxygen exposure levels (e.g., cataracts).

Product/Deliverables:

Initial product will be ground-based studies. Study results will be combined with other ground studies (i.e. NEEMO Oxidative Damage study) to determine if a countermeasure is needed against oxidative damage from an elevated oxygen environment. If a countermeasure is needed, ground-based studies will be solicited, followed by flight validation studies.

Required Delivery Milestone:

Study will be completed by 2013 and data compiled with other oxidative studies. If countermeasure is needed, ground-based studies solicited and performed 2013-2016. Follow-on flight validation studies will be performed 2017-2020 and countermeasures delivered by 2020. If a countermeasure to protect for cataracts is required, it is needed as soon as possible.

Required Platforms:

Ground-based studies, ISS required for validation of any needed countermeasures

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

EVA Oxidative Damage Study – TBD

Current 2007 NRA solicitation (NNJ07ZSA002N) requests studies to determine whether performance of EVA increases oxidative damage. The study should examine if antioxidant supplements mitigate risks of in-flight oxidative damage without untoward negative side effects and if extravehicular activities increase oxidative damage.

Product/Deliverables:

Initial product will be ground-based studies. Study results will determine if a countermeasure is needed against oxidative damage from EVA performance. If a countermeasure is needed, ground-based studies will be solicited, followed by flight validation studies.

Required Delivery Milestone:

Study will be completed by 2013 and if countermeasure is needed, ground-based studies will be solicited and performed 2013-2016. Follow-on flight validation studies will be performed 2017-2020 and countermeasures delivered by 2020. If a countermeasure to protect against oxidative damage is required, it is needed as soon as possible.

Required Platforms:

Ground-based studies, ISS required for validation of any needed countermeasures

Project/Organization Responsible for Implementation of Activity:

NSBRI - via NRA

N8: What are the energy/nutrient requirements of EVA? What is the best delivery system for these nutrients?

EPSP5: What are the energy/hydration requirements and associated waste management requirements of EVA, and what kind of integrated delivery/management systems can be supported in an EVA suit?

Activity:

Determine Energy, Nutrient, Hydration and Waste Management Requirements

Work with flight surgeons and with experts in the JSC Nutritional Biochemistry Lab and the JSC Water and Food Lab to analyze data collected in EPSP3 and EPSP4 to quantify the water and nutrients required for surface EVA operations. These data will then drive requirements for waste management systems and EVA food/hydration requirements (SHFH).

The results of this analysis will be compared with Level II requirements addressing nutrition and hydration that are currently in the Human Systems Integration Requirements (HSIR) document (CxP 70024) and will be used to generate Level III and Level IV requirements.

Product/Deliverables:

Recommendations for nutrition and hydration requirements

Recommendations for waste management system requirements

Required Delivery Milestone:

Analysis will be complete by FY10 to provide inputs to Suit Configuration 2 Systems Requirements Review which will take place in FY11.

Required Platforms:

Statistical analysis and modeling

Project/Organization Responsible for Implementation of Activity:

EPSP

Activity:

Evaluate Concepts for Nutrient and Water Delivery System

Work with experts in Advanced Food Technology Project and the JSC Nutritional Biochemistry Lab to develop concepts for the format of nutrition and hydration sources (energy bar, gel, etc.). Work with crew office to evaluate concepts and get crew consensus.

Work with suit design team to develop concepts for nutrition and hydration delivery systems and waste management systems. Evaluate concepts in ground tests.

Product/Deliverables:

Recommendations for nutrient and water delivery systems

Recommendations for waste management systems

Required Delivery Milestone:

A majority of the studies will be completed by the end of FY09 in order to provide inputs to Suit Configuration 1 (initial capability: launch/abort/entry and microgravity EVA) Interim Design Review (FY09) and Suit Configuration 2 (lunar surface operations) Systems Requirements Review (FY10). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15. Where needed, preliminary data will be used for inputs to Suit Configuration 1 Preliminary Design Review (end of FY08).

Required Platforms:

lunar analog testing environments

Project/Organization Responsible for Implementation of Activity:

EPSP

Activity:

Evaluate Nutrient Delivery Systems and Waste Management Systems in Suit.

Evaluate nutrition/hydration delivery systems and waste management systems in prototype and qualification unit suits. Follow-on flight validation and optimization studies with flight suits will occur during lunar surface operations.

Product/Deliverables:

Evaluation of prototype, qualification unit and flight article suits per standard measures with inputs to design updates as needed.

Required Delivery Milestone:

Suit Configuration 1 development and qualification testing will be complete by the System Acceptance Review in 2012. Suit Configuration 2 development and qualification testing will be complete by the System Acceptance Review in 2017. Evaluation of flight article suits will occur during lunar surface operations.

Required Platforms:

Lunar analogs such as Partial Gravity Simulator (Pogo) and parabolic flight

Lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Constellation EVA Systems Project Office

N4: Do countermeasures impact nutrition?

Activity:

The HHC Element will collaborate with the Space Medicine Division (SD) to determine how various countermeasures impact nutrition (TBR-5).

Product/Deliverables:

TBD

Required Delivery Milestone:

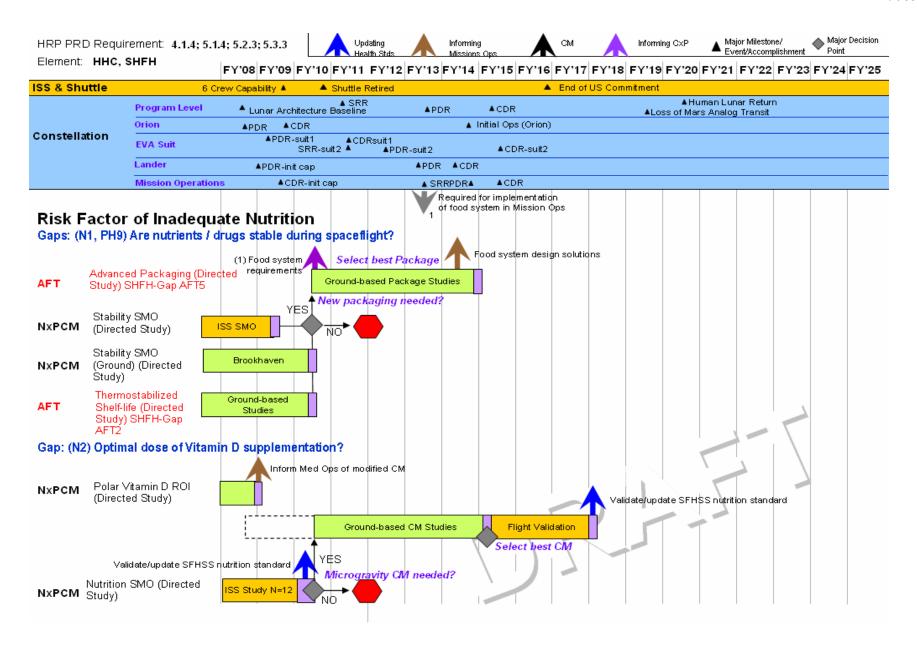
TBD

Required Platforms:

TBD

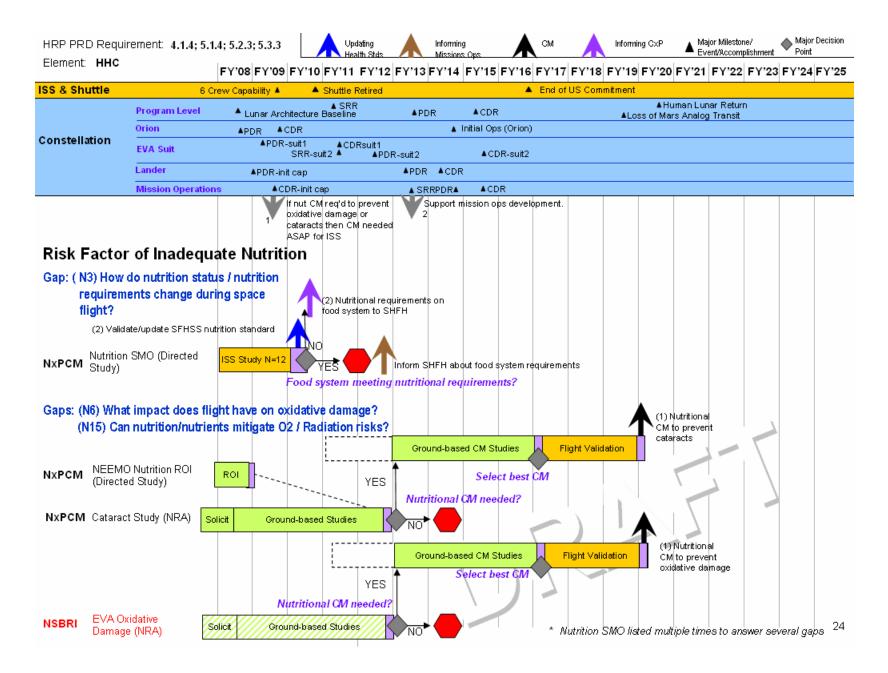
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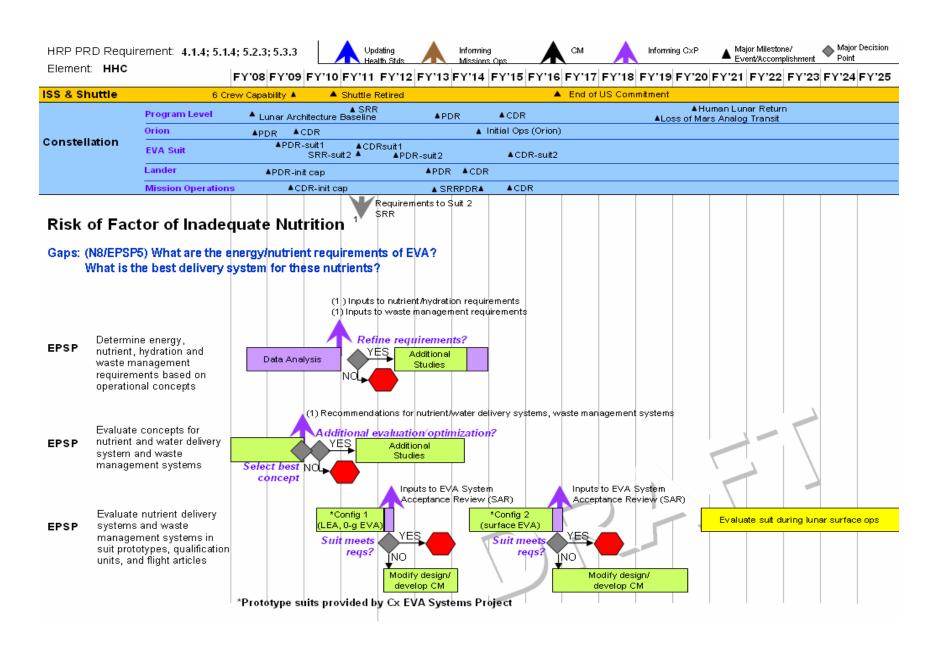
SD



Graphics

Major Decision HRP PRD Requirement: 4.1.4; 5.1.4; 5.2.3; 5.3.3 Informing CxP Element: HHC; SD FY'08|FY'09|FY'10|FY'11|FY'12|FY'13|FY'14|FY'15|FY'16|FY'17|FY'18|FY'19|FY'20|FY'21|FY'22|FY'23|FY'24|FY'25 ISS & Shuttle 6 Crew Capability A ▲ End of US Commitment Shuttle Retired ▲ SRR Lunar Architecture Baseline ▲ Human Lunar Return **Program Level ▲**CDR **▲**PDR ▲Loss of Mars Analog Transit Orion ▲ Initial Ops (Orion) **▲PDR ▲CDR** SRR-suit2 CDRsuit1 Constellation ▲PDR-suit1 **EVA Suit** ▲PDR-suit2 ▲CDR-suit2 Lander ▲PDR ▲CDR ▲PDR-init cap Mission Operations ▲CDR-init cap ▲ SRRPDR▲ **▲**CDR If nut CM regid to mitigate mineral/metal loss Standard update regid to support then CM needed ASAP for ISS mission ops development. Risk Factor of Inadequate Nutrition Gap: (N4) Do CM impact nutrition? Yearly status reports HHC Collaborations with SD 23





6.0 RISK OF INADEQUATE FOOD SYSTEM -D X C

Note: This risk encompasses two different risks from the PRD, "Risk Factor of Inadequate Nutrition" and "Risk Factor of Inefficient Food System". When the PRD was baselined, an action was given to assess these risks for possible combination. This combination is the result of that assessment.

If the food system does not adequately provide for food safety, nutrition and acceptability, then crew health and performance and the overall mission may be adversely affected. Furthermore, if the food system uses more than its allocated mission resources, then total required mission resources may exceed capabilities, the mission deemed unfeasible, or allocation of resources to other systems may be unduly constrained.

Operational Relevance and Risk Context

The paramount importance of the food system in a long duration manned exploration mission should not be underestimated. The food system provides not only the nutrients needed for the survival and health of the astronauts but it also enhances the psychological well being of the crew by being a familiar element in an unfamiliar and hostile environment. Inadequacy of a food system can be influenced by four criteria: safety, nutrition, acceptability and an imbalance of vehicle resources such as mass, volume and crewtime. Since quality loss, including nutrition and acceptability, will occur over the shelf life of the food, efforts are needed to improve understanding of the nutritional content of the food when consumed and how much variety, acceptability, and ease of use is required for different duration missions. Research areas may include: shelf life studies including the effects of time, temperature and radiation, improvement in food preservation, improvement in food packaging, and testing to determine effects of the space environment and length of mission on food acceptability, variety, and ease of use. Research is also required for the food system required during EVA and contingency suited operations. The research will consider requirements to comply with the mission resources such as mass, volume, power, and crewtime.

Priorities

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Critical To Quantify and Reduce Prior to the Mars Mission.

Gaps

AFT1: What are the nutrient-dense foods that could support the high metabolic rates of lunar EVAs?

Activity:

Nutrient-Dense Food Development

Once nutritional requirements have been determined, and the requirements for food bars or beverages have been established, then the development of a nutrient dense food system can be developed for in-suit consumption. The initial work will concentrate on determining whether commercially available items are available. If that is not the case, then food items will be developed. Support for the in-suit delivery system integration will also be provided.

Product/Deliverables:

- Specifications for the in-suit food items
- Development of an adequate number of in-suit food items per mission scenarios with the appropriate nutrition, acceptability and shelf life
- Packaging that will integrate with the EVA suit

Required Delivery Milestone:

Requirements for EVA Foods in 2011; Integrate with in-suit delivery system FY2014

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

AFT

AFT2: What are the nutrition and acceptability of space foods at the time of crew consumption?

The nutrition requirements, determined by the Human Health and Countermeasures Element, are delivered via the food system and through supplementation. Packaged foods are processed, which can reduce the nutritional content. In addition, the crew often does not consume all of their food during a mission. It is expected that improving the nutritional content and the acceptability of the food system will increase crew consumption which will ensure good nutritional status.

Activity:

Effect of the Retort Process on Nutritional Content of Food

The nutritional content of the flight food items is not measured. The actual macronutrients and some minerals are determined chemically. However, the other nutrients such as vitamins are only determined through a computer program which calculates the combined nutritional content based on the food products formulation. The computer program does not take into account the loss of nutrients during the thermostabilization process.

Product/Deliverables:

Review literature to better understand what are the potential effects of the retort process. Optimize time/temperature processing conditions for each specific thermostabilized food product that NASA produces.

Measure nutrient content of the finished product.

Required Delivery Milestone:

FY2015 – Required as a design solution to support the food system for operations on the lunar surface. However, if information is available prior to this, it could be used to influence the food system for the ISS.

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

AFT

Effect of the Freeze-drying Process on Nutritional Content of Food

The nutritional content of the flight food items is not measured. The actual macronutrients and some minerals are determined chemically. However, the other nutrients such as vitamins are only determined through a computer program which calculates the combined nutritional content based on the food products formulation. The computer program does not take into account the loss of nutrients during the freeze drying process.

Product/Deliverables:

Review literature to better understand what the potential effects are.

Optimize time/temperature processing conditions for each specific freeze-dried food product that NASA produces.

Measure nutrient content of the finished product.

Required Delivery Milestone:

FY2015 – Required as a design solution to support the food system for operations on the lunar surface. However, if information is available prior to this, it could be used to influence the food system for the ISS.

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

AFT

Activity:

Stability of Pharmacotherapeutic and Nutritional Compounds: Stability SMO (Flight)

This protocol involves investigative physical/chemical analyses of both medications and food items returned from STS and ISS along with corresponding lot-matched controls stored on ground in a controlled environment. This experiment has two (2) sub-payloads attached to it. See the Risk of Therapeutic Failure Due to Ineffectiveness of Medications for the Pharmacology sub-payload. The Nutritional Sub-Payload will identify vitamins and amino acids at risk for degradation in space food supply; identify changes in fatty acids of foods flown on ISS; and characterize degradation profiles of the unstable nutrients. This study will provide critical information about the preservation of vitamins and nutrients in food during space flight and susceptibility of vitamins in the space food system to adverse environmental factors and storage encountered during space missions.

Product/Deliverables:

The initial product is an ISS study.

Required Delivery Milestone:

ISS Stability study performed from 2006-2009.

Required Platforms:

ISS required for proper radiation doses on food samples.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study; with collaboration with the Advanced Food Technology Project

Activity:

Assessment of Nutrient Stability in Space Using Ground-based Simulation of Spacecraft Environmental Factors: Stability SMO (Ground)

Nutritious food and effective medication availability on the spacecraft remains a critical issue for mission success and crew health and safety. Ground-based evidence indicates that many vitamins are destroyed and fatty acids are oxidized (and therefore rendered dangerous or useless) by different types of radiation and during long-term storage. This study uses radiation exposure to test the stability of various food and pharmaceutical components and will be compared to ongoing flight data that is being collected.

Product/Deliverables:

The initial product is a radiation study using ground-based radiation sources (Brookhaven, university or hospital facilities).

Required Delivery Milestone:

Ground Stability study performed from 2006-2010;

Required Platforms:

Ground-based radiation sources (Brookhaven, university or hospital facilities) required for assessment of radiation doses on food samples.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study; with collaboration with the Advanced Food Technology Project

Activity:

Effect of Space Radiation on Nutrition and Acceptability

Preliminary results from some NASA-funded research indicate that some functionality and quality changes occur in foods and food ingredients at lower radiation levels. If results from the ground and flight Stability Studies indicate nutrient loss due to radiation, further research will be required to determine quality changes at appropriate dosage levels for Mars and lunar missions and the appropriate countermeasures.

Product/Deliverables:

Summary of radiation effects on food using literature and external NASA-funded research. Conduct shelf life test to determine the changes in quality and nutritional content of foods over time when exposed to the appropriate dose of radiation.

Food system design solutions to countermeasure the effects of radiation.

Required Delivery Milestone:

Constellation Program informed of food system requirements in 2010; Mission operations informed in 2014 of any food system design solutions. The food system requirements are needed by FY13 to support implementation of the food system in mission operations development.

Required Platforms:

Ground based study.

Further ISS or lunar testing may be required depending on results from ISS Stability Study and other data collected.

Project/Organization Responsible for Implementation of Activity:

AFT

Activity:

Effect of Time and Temperature on Nutrition and Acceptability; Thermostabilized Shelf-Life Test to Determine Shelf-Life of Food Items Stored at Room Temperature

Shelf-live on the current thermostabilized food products have never been determined. Thirteen food items with varied formulations have been placed in accelerated shelf life testing. In addition three bulk ingredients (for preparation of a lunar outpost mission) were placed into accelerated shelf life testing. Sensory and analytical changes are measured over the three year test.

Product/Deliverables:

This will ultimately result in a list of foods and/or preparation methods that support lunar operations.

Required Delivery Milestone:

FY2015 – Required as a design solution to support the food system for operations on the lunar surface. However, if information is available prior to this, it could be used to influence the food system for the ISS.

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

AFT

AFT3: What are the psychosocial requirements for the food system for different mission lengths (TBR-6)?

If the food is not acceptable to the crew, then the crew will not eat an adequate amount of the food and will be compromised nutritionally. Anecdotal reports have suggested that the food does not taste the same in microgravity. Other reports indicate that the crew craves different foods on-orbit as compared to on-Earth. In addition, the crew has reported that they tire of certain foods over the 6-month ISS mission.

Sensory Qualities in Microgravity

Determine effect of changes in aroma detection due to fluid shift and lack of convection of air in microgravity.

Determine effects of "long term acceptability".

Validate with ISS Study incorporating surveys of food taste.

Product/Deliverables:

Requirements on the food system for long-duration operations

Required Delivery Milestone:

~FY2019 (Note, Need date for Lunar Outpost SRR is TBD.)- Required to define requirements on food system for long-duration Lunar outpost and Mars Missions. However, if information is available prior to this, it could be used to influence the food system for the ISS.

Required Platforms:

Ground

Validation on ISS

Project/Organization Responsible for Implementation of Activity:

AFT- Directed Study

Activity:

Variety, Acceptability, and Usability Requirements Development (TBR-7)

Determine requirements on the food system for variety of foods, taste acceptability and usability (performed primarily through taste panels and surveys).

Product/Deliverables:

Requirements on the food system for long-duration operations

Required Delivery Milestone:

~FY2019 (Note, Need date for Lunar outpost SRR is TBD) - Required to define requirements on food system for long-duration Lunar outpost and Mars Missions. However, if information is available prior to this, it could be used to influence the food system for the ISS.

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

AFT- Directed Study

Activity:

Psychosocial Requirements of Food Operations (eating together, holiday foods, etc)

Requirements and guidelines development process requiring little if any research. This requirements development will consist of recommendations to mission ops for times for eating, eating together, special foods, holiday foods, etc. Requirements will be developed in conjunction with the crew office and AFT lab.

Product/Deliverables:

Requirements on food system and mission operations

Required Delivery Milestone:

~FY2019 (Note, Need date for Lunar outpost SRR is TBD) - Required to define requirements on food system for long-duration Lunar outpost and Mars Missions. However, if information is available prior to this, it could be used to influence the food system for the ISS.

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

BHP – Directed Study

AFT4: Can a 5-year shelf life packaged food system be developed for extended NASA missions?

Shelf-life criteria are safety, nutrition, and acceptability. Any of these criteria can be the limiting factor in determining the shelf-life. The ISS food system currently has an 18 month shelf life. To achieve that shelf life, some foods are over wrapped with a high barrier material. Results from ongoing shelf life studies of thirteen thermostabilized food items suggest that the shelf life of the foods range from 16 months to 8 years, depending on formulation.

Activity:

Department of Defense (DoD) Collaboration

Although the commercial food industry requirements are not compatible with NASA's requirements, the Combat Feeding Program (DoD) requirements are compatible with NASA. Both NASA and DoD require long shelf life, shelf stable food items with high barrier packaging. Both also require minimal packaging. The DoD Combat Feeding Program when conducting their research uses collaborations of industry, government, and academia experts. Currently, the DoD has an active packaging research program as well as a program investigating emerging preservation technologies. These preservation technologies should result in FDA approval of high pressure processing and microwave sterilization for shelf stable products.

Product/Deliverables:

Recommendations for advanced food packaging and preservation technologies for shelf stable foods

Required Delivery Milestone:

~FY2023 (Note, Need date for Lunar outpost CDR is TBD) - Required to meet requirements on food system packaging for long-duration Lunar outpost and Mars Missions. However, if information is available prior to this, it could be used to influence the ISS food system if it would positively influence its long-term nutrient stability or reduce food logistics.

Required Platforms:

Ground Laboratory

Project/Organization Responsible for Implementation of Activity:

AFT in collaboration with DoD

AFT5: How can package mass and volume be reduced without compromising food quality?

The food system is a significant contributor to the mass and volume in the vehicle. A reduction in mass and volume through formulation or packaging would benefit the program.

Activity:

Advanced Packaging Material Development

Currently the packaging used for freeze-dried foods and natural form foods does not have adequate oxygen and moisture barrier properties to allow for an 18-month shelf life for ISS. Therefore, those foods are over wrapped with a second foil-containing package which has higher barrier properties. The packaging material used for the thermostabilized, irradiated, and beverage items contain a foil layer to maintain product quality over at least the required 18 month shelf life. Although foil in the packaging material provides excellent oxygen and moisture barrier properties, it is not compatible with microwave sterilization and high pressure processing. The foil layer within the food package may also provide complications if the decision is made to incinerate the trash on the lunar or mars surface. These emerging preservation technologies have the potential of providing NASA with a higher quality food system Therefore, research to develop a packaging material that has the barrier properties of foil without the foil is necessary.

- Packaging Shelf Life Study determine whether any current flight packaging can be used as the primary package for freeze-dried and natural form foods.
- Packaging Workshop determine which emerging or commercially available technologies can be used for NASA Exploration missions.
- External Research Project development of new high barrier, foil-free packaging material

Product/Deliverables:

Food packaging technologies that reduce the overall mass and volume required for the food system

Required Delivery Milestone:

FY2015 – Required as a design solution to support the food system for operations on the lunar surface. However, if information is available prior to this, it could be used to influence the food system for the ISS to reduce food logistics.

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

AFT, - Directed Study

Reduced Mass in Food

In order to provide a lower mass and volume food system for the Constellation Program, changes in product formulation may be necessary. Changes to consider are removing some water from the total food system, increasing fat content, or increasing nutrient density of the food items.

Product/Deliverables:

Trade studies to consider options to reduce mass of food. Determine best case scenario for further development.

Determine commercial availability of foods with preferred scenario.

Develop technologies for food product development if not commercially available.

Required Delivery Milestone:

FY10 – Required for first ISS Orion mission (<u>Justification – Current food system overweight.</u> Challenged to reduced mass from 4 lbs to 2.5 lbs per day)

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

AFT- Directed Study

AFT6: How can the mass and volume of the Lunar food system be reduced and how can it serve as a test bed for future Mars missions (TBR-8)?

By incorporating plant growth, food processing and food preparation, the mass and volume of the food system could be reduced.

Activity:

Partial Gravity and Atmospheric Effects on Food Processing and Preparation

Heat and mass transfer are affected by partial gravity and reduced atmospheric pressure. When preparing raw foods into edible ingredients, it is necessary to reach a certain temperature/time combination to insure safety and certain functionality. It is being proposed that the lunar habitat will maintain an 8 psi atmospheric pressure. At that pressure, the boiling temperature for water is $181^{\circ}F$. Research needs to be conducted to determine whether the 1/6 G of the lunar surface and the 8 psi of the habitat will result in incomplete heating. If incomplete heating does occur, research will be required to determine countermeasures.

Determine whether there is incomplete cooking.

If there is incomplete cooking, what is the mitigation strategy?

Product/Deliverables:

Used as an input to the trade study (see next activity).

Ultimately results in requirements on the Lunar Outpost Food System regarding food preparation and/or processing equipment.

Required Delivery Milestone:

Completion of study by FY2013 to support trade study.

If the decision is to develop a food system with surface processing and preparation, then this decision would be required by FY 2015 to prepare for the ultimate delivery ~FY2019 (Note, Need date for Lunar outpost SRR is TBD) to define requirements on food system for long-duration Lunar outpost and Mars Missions. This study supports this decision process.

Required Platforms:

Ground with validation on ISS or lunar surface

Project/Organization Responsible for Implementation of Activity:

AFT - Directed Study or RFP

Activity:

Food Processing vs. Packaged Food System Trade Study (TBR-9)

Preliminary studies suggest total mass of the food system can be reduced if the food system moves more towards a bioregenerative food system. In a bioregenerative food system vegetables and fruit would be freshly grown on the lunar or Mars surface and baseline crops such as soybeans, wheat, rice, peanuts, and dried beans would be grown or launched in bulk from Earth. The baseline crops would be processed into edible ingredients. The edible ingredients and freshly grown fruits and vegetables would be used in preparing meals in the galley. Some packaged food would likely be required.

Further studies are required to determine the magnitude of mass savings and the effect on other mission resources such as power, crewtime, and recycling of water used in the processing. These studies will also identify the equipment that would be required to be built for the lunar surface test.

Trade study that considers efficiencies and adequacies of the two food systems with a recommendation to the Program

Product/Deliverables:

Requirements on the Lunar Outpost Food System regarding food preparation and/or processing equipment

Required Delivery Milestone:

If the decision is to develop a food system with surface processing and preparation, then this decision would be required by FY 2015 to prepare for the ultimate delivery ~FY2019 (Note, Need date for Lunar outpost SRR is TBD) to define requirements on food system for long-duration Lunar outpost and Mars Missions. This trade study supports this decision process.

Required Platforms:

Ground

Project/Organization Responsible for Implementation of Activity:

AFT – Directed Study

Develop Processing and Preparation Equipment and Procedures

If a bioregenerative food system is used, then miniaturized processing equipment will need to be built. It is unlikely that there will be commercial equipment appropriately sized for a lunar or Mars mission. The preparation equipment for the galley will likely be commercially available gourmet kitchen appliances that will need to be modified for the Lunar missions.

- Technology Development for several pieces of food processing equipment and procedures to develop safe and high quality edible ingredients for further preparation in galley
- Technology Development for several pieces of food preparation equipment and procedures to develop safe and high quality recipes in galley

Product/Deliverables:

Food system processing technologies for a Lunar outpost or Mars mission.

Required Delivery Milestone:

~FY2019 (Note, Need date for Lunar outpost SRR is TBD) to provide design solution for the food system for long-duration Lunar outpost and Mars Missions.

Follow-on validation and optimization for Mars missions to occur in lunar ops (Date TBD).

Required Platforms:

Ground with validation on lunar surface

Project/Organization Responsible for Implementation of Activity:

AFT – Directed Study or RFP

Activity:

Vegetable Growth

In order to provide the crew with fresh food on surface Lunar and Mars missions, fruits and vegetables will be grown hydroponically in environmentally-controlled growth chambers. Significant research has been conducted to determine growth conditions and plant sensitivities to environmental changes. However, further research is required to finalize the environmental conditions for the plant growth.

Since these fruits and vegetables may be consumed uncooked, research is required to determine the handling procedures pre- and post-harvest to insure safety.

Product/Deliverables:

Growth procedures for fresh vegetables and fruits

Handling procedures to ensure safe, uncooked foods

Required Delivery Milestone:

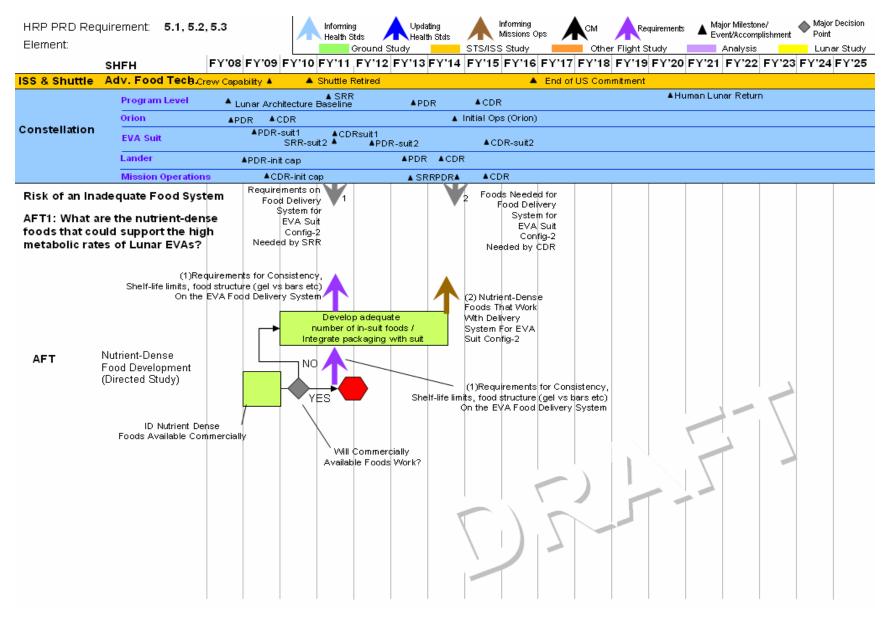
~FY2019 (Note, Need date for Lunar outpost SRR is TBD) to provide design solution for the food system for long-duration Lunar outpost and Mars Missions.

Required Platforms:

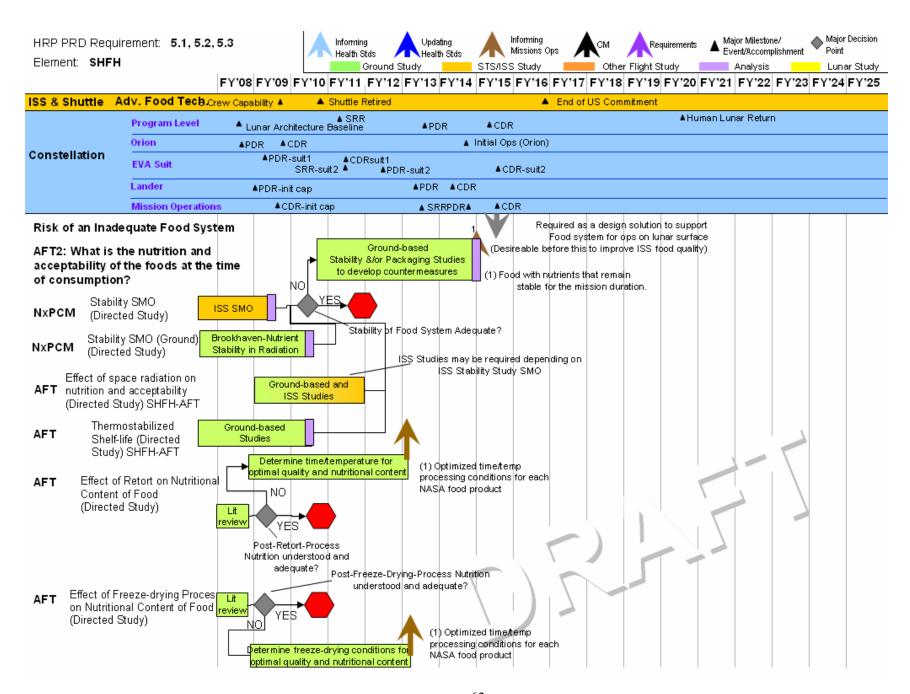
Ground with validation on lunar surface

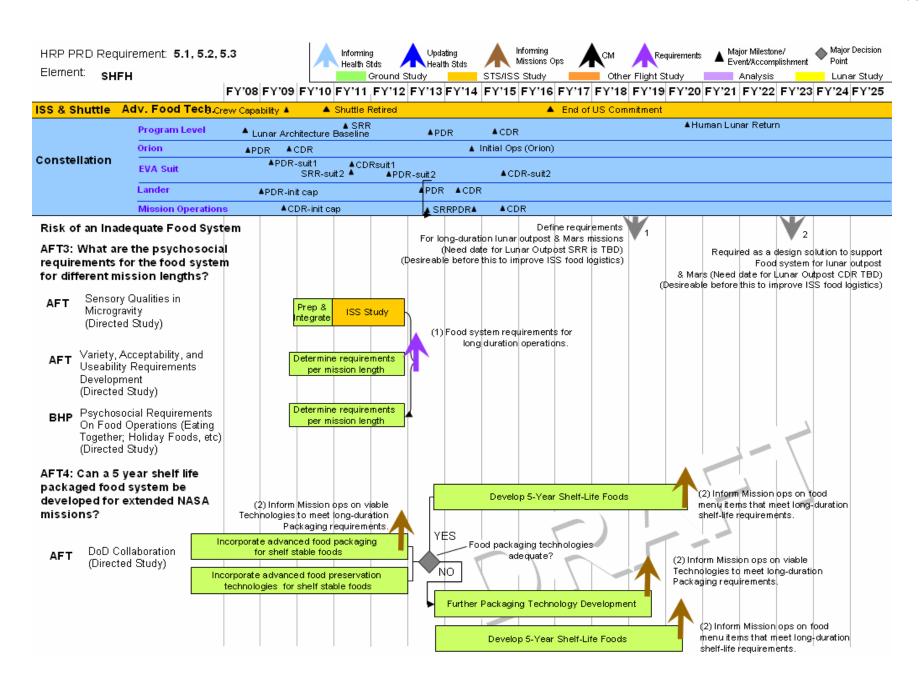
Project/Organization Responsible for Implementation of Activity:

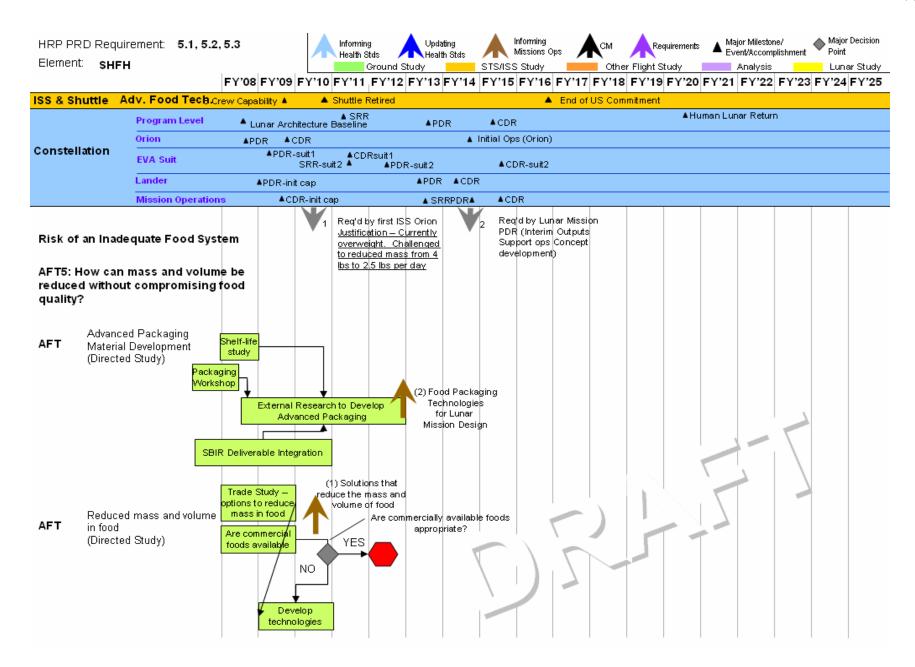
AFT and/or Crop Systems team (TBD)

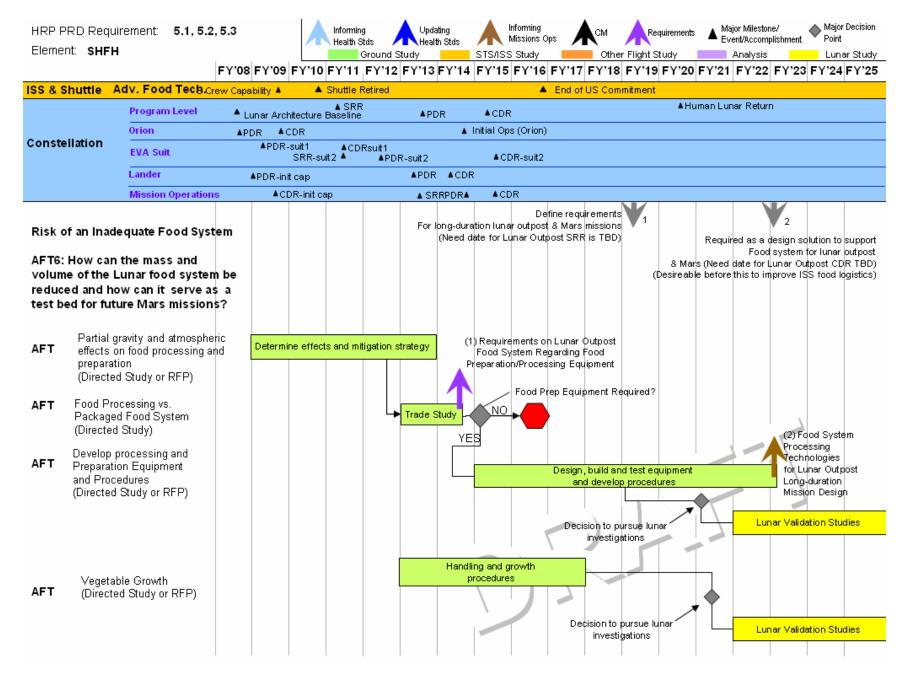


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HRP-47065

7.0 RISK OF BEHAVIORAL AND PSYCHIATRIC DISORDERS -D X C

Behavioral issues are inevitable among groups of people, no matter how well selected and trained. Space flight demands can heighten these issues. The Institute of Medicine (IOM) report, Safe Passage, notes that Earth analog studies show an incidence rate of behavioral problems ranging from 3-13 percent per person per year. The report transposes these figures to 6-7 person crews on a 3-year mission to determine that there is a significant likelihood of psychiatric conditions emerging. Impacts of behavioral issues are minimized if they are identified and addressed early. The HRP must provide the best measures and tools to monitor and assess mood and to predict risk for, and management of, behavioral and psychiatric conditions prior, during and following space flight.

Operational Relevance and Risk Context

BHP research addresses the risk of behavioral and psychiatric conditions developing during or following an Exploration Mission. Early detection of stress or other risk factors during spaceflight is imperative to deter development of behavioral or psychiatric conditions which could seriously harm and negatively impact the individual or the crew, and pose serious consequences for accomplishing mission objectives or jeopardizing the mission altogether. Toward this end, BHP is developing methods for monitoring behavioral health during a Lunar and Mars Mission, and adapting/refining various tools and technologies for use in the spaceflight environment. These measures and tools will be used to monitor, detect and treat early risk factors. BHP will utilize analogs to test, further refine, and validate these measures for Exploration Missions. BHP also develops countermeasures for maintaining behavioral health and enhancing performance during long duration isolated, confined, and highly autonomous missions; provides recommendations regarding BHP best practices; and, provides updates for behavioral health and performance Standards.

The BHP element includes two additional risks – increased human performance errors due to sleep loss, fatigue, work overload, and circadian desynchronization; and, increased errors due to poor team cohesion and performance, inadequate selection/team composition, inadequate training, and poor psychosocial adaptation. The three risks are highly interrelated; the occurrence or mitigation of one risk can be a contributing factor affecting another. As a result, BHP gap-related activities and deliverables may sometimes address more than one risk.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission

Mars Mission: Critical to Quantify and Reduce Prior to the Mars Mission

Gaps

BHP 3.1.1: What are the best assessment measures to detect behavioral and psychiatric disorders? (Priority 1)

BHP 3.2.1: What countermeasures can be developed to maintain behavioral health during spaceflight missions? (Priority 2)

Currently a computerized "psychologist" is under development through the NSBRI, in conjunction with Medical Operations and the Astronaut Office; this "smart" technology allows a crewmember on a long duration Lunar or Mars Mission to evaluate signs or symptoms of early depression and anxiety, and receive therapy as desired.

The computer-based aid for addressing depression (based on problem-solving therapy), is not designed to replace the clinician; rather, it will complement the service of the aerospace psychiatrist during a long duration Exploration Mission. The tool enhances privacy, confidentiality, and support of the astronaut during autonomous missions such as the Mars Mission which will have considerable communication delays between space crew and ground support. It allows the astronaut to educate him/herself, augmenting the one-on-one private physician consultation. At times when such consultation is not feasible, it will serve as a diagnostic tool and autonomous countermeasure that is available 24/7, with feedback to the individual, aerospace psychiatrist, and the crew surgeon.

Activity:

Refine and Validate Tool for Early Detection and Mitigation of Depression (TBR-10)

Ground based studies (laboratories and analogs) 2008-2010 to refine and test the effectiveness and feasibility of tool. Flight validation 2011-2013. If technology is not effective or feasible, subsequent research activity will pursue other measures.

Product/Deliverables:

- 1) Tool to detect and treat depression early.
- 2) Updates to Standards.

Required Delivery Milestone:

Tools to detect and treat depression delivered in 2013. Standard updated by 2012.

Tools required by 2014 for Mission Ops implementation.

Required Platforms:

Use of space analogs to refine and validate tool (2008-2010).

Flight validation on ISS; the ISS will emulate the transit environment to Mars.

Project/Organization Responsible for Implementation of Activity:

NSBRI

Due to the delayed communication that will exist between the space crew and the ground during an Exploration Missions, flight surgeons have stated the need for unobtrusive monitoring tools, transparent to the flight crews, that will help detect if an astronaut is demonstrating or otherwise evidencing high levels of stress and fatigue. These tools are to require minimal crew time and effort. The tools will allow the crewmember the ability for self-assessment, providing immediate feedback so that countermeasures can be administered in a timely manner, if necessary.

Currently, two monitoring technologies are planned. These technologies, to be adapted specifically for Exploration Missions, are already under development through previous work

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of the researchers with other agencies. NASA is able to leverage such technologies, and with some refinement, adaptations, and validation, provide these tools for Lunar and Mars Missions.

Activity:

Refine/Adapt Unobtrusive Monitoring Technologies

Facial Monitoring Technology

Laboratory studies are evaluating whether optical computer recognition algorithms based on changes in facial expressions can discriminate stress induced by low versus high workload. Following refinement of the tool to detect changes despite fluid shifts that can occur during spaceflight, it is anticipated that the tool will be validated in analog environments (including NEEMO and HMP), then validated on ISS.

Voice Acoustics Monitoring Technology

This speech monitoring technology will automatically and unobtrusively monitor the effects of stress and neurological impairment on astronauts' ability to perform in extended missions. The system detects cognitive decrements resulting from hypoxia and radiation, and can discriminate between high and low stress conditions.

Research activities include continued use of space analogs to adapt and validate effectiveness of the tool for the spaceflight environment. It is anticipated that the technology will also undergo in-flight validation on ISS.

Product/Deliverables:

- 1) Facial Monitoring Technology, (i.e., the Optical Computer Recognition Tool unobtrusive, passive technology that assesses individual responses to stress)
- 2) Voice Acoustics Monitoring Technology (unobtrusive, passive technology that assesses individual responses to stress, as well as radiation and hypoxia effects)
- 3) Updates to Standards (if applicable).

Required Delivery Milestone:

Technologies to be validated in-flight by 2012; if effective, Crew Health Standards to be updated by 2012 and technologies to be delivered by 2012. The effectiveness of the tools largely depends on ISS validation phase, as technologies that monitor an individual's coping involve analyzing facial movements and acoustic patterns, which can be affected by microgravity or other aspects of the isolated confined space environment.

Technologies are required for Mission Operations Implementation by 2014.

Required Platforms:

Ground studies to adapt technologies for spaceflight; analogs include NEEMO, Haughton Mars Project (HMP), Mt. Everest, and potentially other Isolated, Confined and Extreme (ICE) Environments. Require the ISS for validation because of the parameters being monitored may be affected by microgravity. The ISS will emulate the transit environment to Mars. Involves collaboration with NSBRI.

Project/Organization Responsible for Implementation of Activity:

NSBRI

BHP 3.1.2: What aspects of cognition decline or change during LDM spaceflight, during stays on surfaces, and following LDM, as a function of LDM itself or specific activities during LDM? (Priority 2)

Activity:

Assess Cognitive and Neurostructural Changes

Evidence Gathering

Evidence gathering and review from space analogs and spaceflight. A questionnaire administered to crews returning from long duration missions in space, and mining of existing data from spaceflight will offer insight into potential *clinical cognitive changes*.

Evidence gathering and review from space analogs, pre-flight, in-flight, and post-flight. A review of medical data from analogs may reveal whether physical *neurostructural changes* exist after long duration missions in extreme conditions, and may propose potential measurement methods for upcoming missions to the Moon and Mars. Collaborative studies on animals with radiation may also provide evidence.

If evidence reveals that additional countermeasures are required beyond what BHP has developed/is developing, subsequent research activity will ensue to develop additional countermeasures

Product/Deliverables:

- 1) Recommendations based on evidence gathered regarding clinical cognitive changes.
- 2) Recommendations based on evidence gathered of neuro-structural changes.
- 3) Update Standards.

Required Delivery Milestone:

Standards update in 2012. Recommendations (clinical cognitive changes) delivered by 2013. Recommendations (neurostructural changes) delivered by 2016. Continued evidence gathering through Constellation operations.

Recommendations for Mission Ops Requirements Definition for long duration Lunar Missions and Mars Missions, due by 2023.

Required Platforms:

Evidence gathering is primarily a ground based effort utilizing analogs with long duration capability such as Antarctica, with some evidence gathered from long duration ISS (to detect potential clinical cognitive changes).

Project/Organization Responsible for Implementation of Activity:

Directed Study / Collaboration with Radiation

BHP 3.2.2 What are the most appropriate and effective ways for crews to use behavioral health medications in spaceflight? (Priority 3)

Space analogs, such as Antarctica, confirm mood deterioration and increased stress occur in individuals in isolated, confined and extreme environments (ICE); some crewmembers on MIR Missions and ISS have reported similar experiences. Psychotropic medications may be considered helpful in mediating these deleterious effects and in treating behavioral or psychiatric conditions that may arise during Exploration Missions.

Over the next decade, the field of psychopharmacology will undoubtedly continue to develop new medications for the treatment of behavioral and psychiatric disorders. In preparation for long duration Exploration Missions, BHP will collaborate with Medical Operations to review state-of-the-art medications and provide a compendium of best practices. A pharmaceutical armamentarium that covers a broad range of mental disorders, produces minimal side effects, requires no laboratory monitoring and have minimal storage requirements will be needed for long duration Exploration Missions.

Activity:

Develop Electronic Medications Database

In collaboration with Medical Operations and Subject Matter Experts, workshop and data mining to review literature on performance, safety, and side effects of state-of-the-art medications for behavioral and psychiatric disorders.

Product/Deliverables:

Electronic Behavioral Medications Database.

Required Delivery Milestone:

Activity to begin in 2018 and be delivered by 2020, with subsequent updates every four years. Due date for Lunar Mission Ops for Lunar Habitat is 2023.

Required Platforms:

Primarily a ground based effort.

Project/Organization Responsible for Implementation of Activity:

TBD

BHP 3.3.1 What selection and assignment criteria are needed for Exploration Missions? (Priority 3)

Activity:

Develop Selection Criteria for Exploration Missions

New criteria may be necessary for astronaut selection for Exploration Missions. Neuropsychiatric assessment may be helpful in this process, as the biological basis of mood disorders suggests neural biomarkers may provide a more objective method for assessing some psychiatric conditions such as depression. A current NSBRI effort is evaluating and validating a neuroimaging technology for its ability to detect biomarkers of depression and its severity, as well as indicators of treatment resistance.

BHP will collaborate with Med Ops to determine what additional assessment may be utilized. A review of preferred measures within other agencies where crews or small groups embark on expeditions in extreme environments (such as the military) will establish an evidence base for informing BHP screening recommendations prior to Exploration Missions assignment.

These neuropsychiatric screening measures will establish a baseline for each astronaut, which will be helpful if medical issues occur in-flight or post-flight.

Product/Deliverables:

- 1) Recommendations regarding best measures for neuropsychiatric assessment/treatment.
- 2) Inform Standards.

Required Delivery Milestone:

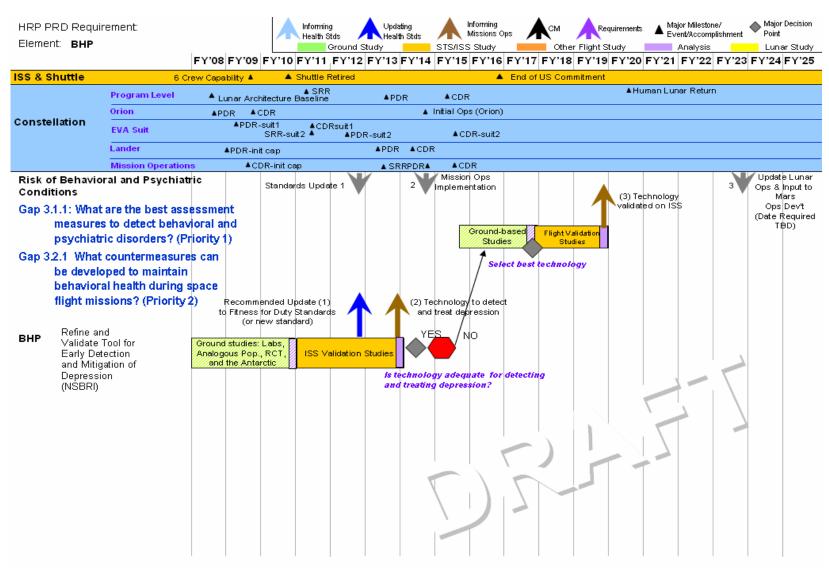
Recommendations for Mission Ops to be delivered by 2013; recommendations due to Mission Ops by 2013

Required Platforms:

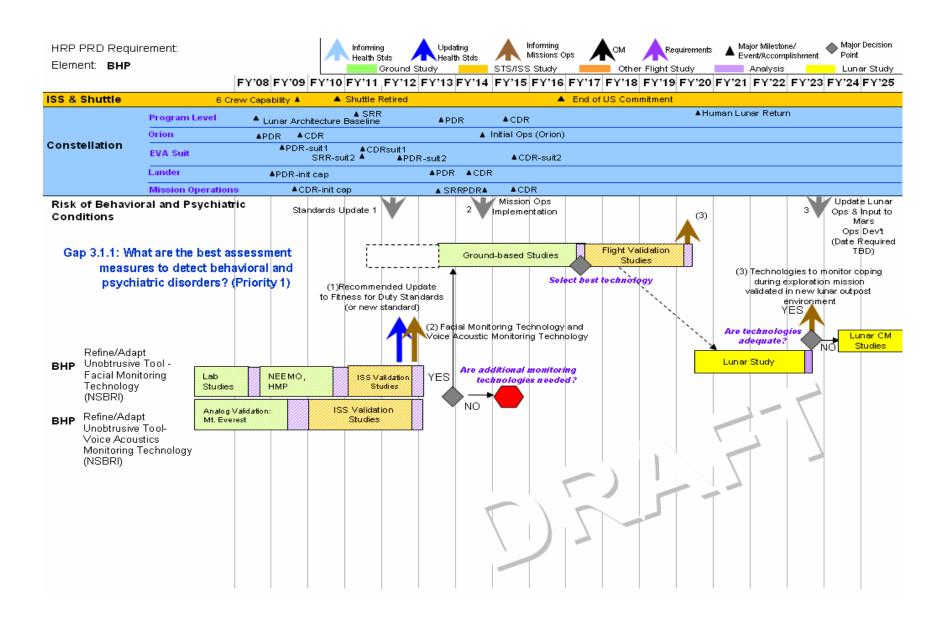
This ground effort primarily involves evidence gathering and collaboration with identified stakeholders.

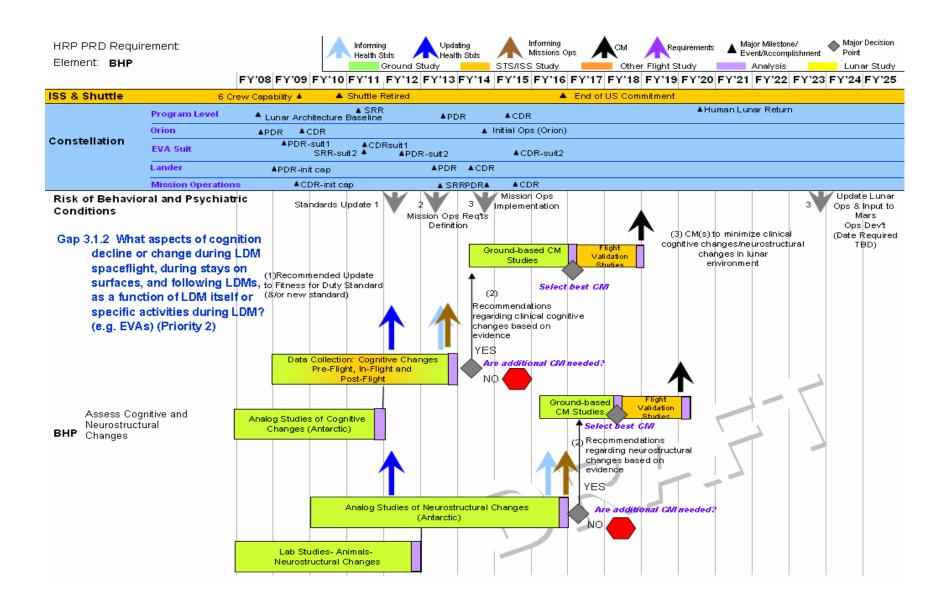
Project/Organization Responsible for Implementation of Activity:

TBD

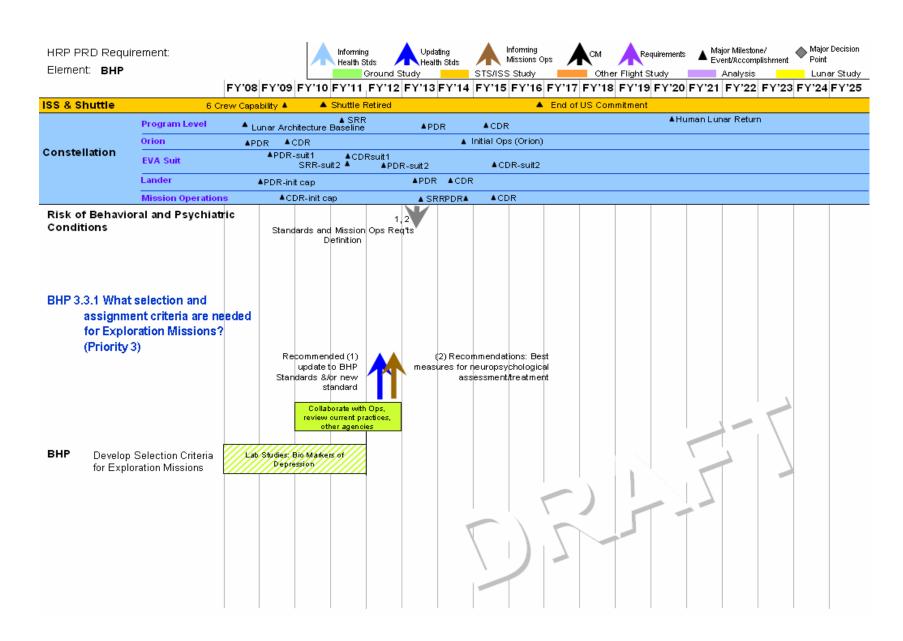


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Major Decision Major Milestone/ HRP PRD Requirement: Informing ▲ Event/Accomplishment Missions Ops Health Stds Health Stds Element: BHP Ground Study STS/ISS Study Other Flight Study Analysis Lunar Study FY'08 FY'09 FY'10 FY'11 FY'12 FY'13 FY'14 FY'15 FY'16 FY'17 FY'18 FY'19 FY'20 FY'21 FY'22 FY'23 FY'24 FY'25 ISS & Shuttle 6 Crew Capability A ▲ Shuttle Retired End of US Commitment ▲Human Lunar Return ▲ SRR Lunar Architecture Baseline **Program Level ▲**PDR **▲**CDR Orion ▲ Initial Ops (Orion) ▲PDR ▲CDR SRR-suit2 CDRsuit1 Constellation ▲PDR-suit1 **EVA Suit** ▲PDR-suit2 ▲CDR-suit2 Lander APDR ACDR ▲PDR-init cap **Mission Operations** ▲CDR-init cap **▲**CDR ▲ SRRPDR▲ Ops CMs needed Risk of Behavioral and Psychiatric To design long-Conditions duration missions Gap 3.2.2 What are the most appropriate and effective ways for crews to use behavioral health (3) Electronic Behavioral Medications Database medications in spaceflight? (Priority 3) Workshop, Review of Upda Develop Electronic BHP Meds (Best Practices) Medications Database tes



- 8.0 RISK OF RADIATION CARCINOGENESIS FROM SPACE RADIATION I X I
- 9.0 RISK OF ACUTE OR LATE CENTRAL NERVOUS SYSTEM EFFECTS FROM SPACE RADIATION I X I
- 10.0 RISK OF DEGENERATIVE TISSUE OR OTHER HEALTH EFFECTS FROM SPACE RADIATION I X I
- 11.0 ACUTE RADIATION RISKS FROM SPACE RADIATION I X I

SRPE INTEGRATED RESEARCH PLAN

1.0 Space Radiation Risks

- 1.1 Risk of Radiation Carcinogenesis from Space Radiation
- 1.2 Risk of Acute or Late Central Nervous System Effects from Space Radiation
- 1.3 Risk of Degenerative Tissue or other Health Effects from Space Radiation
- 1.4 Acute Radiation Risks from Space Radiation

2.0 Operational Relevance Assessment and Recommendations

3.0 Gaps, Mitigation, Deliverables, Platforms, and Responsibility

- 3.1 Radiation Carcinogenesis
 - 3.1.1 Priority
 - 3.1.2 Gaps
 - 3.1.3 Description of Research Approach
 - 3.1.4 Activity
 - 3.1.5 Product/Deliverables/Milestones
 - 3.1.6 Required Platform
 - 3.1.7 Project/Organization Responsible for Implementation of Activity

3.2 Radiation CNS

- 3.2.1 Priority
- 3.2.2 Gaps
- 3.2.3 Description of Research Approach
- 3.2.4 Activity
- 3.2.5 Product/Deliverables/Milestones
- 3.2.6 Required Platform
- 3.2.7 Project/Organization Responsible for Implementation of Activity

3.3 Radiation Degenerative

- 3.3.1 Priority
- 3.3.2. Gaps
- 3.3.3 Description of Research Approach
- 3.3.4 Activity
- 3.3.5 Product/Deliverables/Milestones
- 3.3.6 Required Platform
- 3.3.7 Project/Organization Responsible for Implementation of Activity

3.4 Radiation Acute

- 3.4.1 Priority
- 3.4.2 Gaps
- 3.4.3 Description of Research Approach
- 3.4.4 Activity
- 3.4.5 Product/Deliverables/Milestones
- 3.4.6 Required Platform
- 3.4.7 Project/Organization Responsible for Implementation of Activity

4.0 Background

5.0 Acronyms

Appendix A: 20 Year Strategy

Appendix B: Gantt Charts of SRPE Research Plan (attached)

1.0 Space Radiation Risks

1.1 Risk of Radiation Carcinogenesis from Space Radiation

Space radiation exposure increases cancer morbidity and mortality risk in astronauts. This risk may be influenced by other space flight factors including microgravity, environmental contaminants, nutritional issues, and psychological and physiological stress. Current space radiation risks estimates are based on human epidemiology data for X-rays and gamma-ray exposure scaled to the types and flux-rates in space using radiation quality factors and dose-rate modification factors, and assuming linearity of response. There are large uncertainties in this approach and experimental models imply additional detriment due to the severity of the phenotypes of cancers formed for the heavy ion component of the galactic cosmic rays compared to cancers produced by terrestrial radiation. A Mars mission may not be feasible (within acceptable limits) unless uncertainties in cancer projection models are reduced allowing shielding and biological countermeasures approaches to be evaluated and improved, or unless mission durations are constrained.

1.2 Risk of Acute or Late Central Nervous System Effects from Space Radiation

Acute and late radiation damage to the central nervous system (CNS) may lead to changes in motor function and behavior, or neurological disorders. Radiation and synergistic effects of radiation with other space flight factors may affect neural tissues, which in turn may lead to changes in function or behavior. Data specific to the spaceflight environment must be compiled to quantify the magnitude of this risk using animal models and 2-dimensional or 3-dimensional cell culture models of human or other vertebrate cells. If this is identified as a risk of high enough magnitude then appropriate protection strategies should be employed.

1.3 Risk of Degenerative Tissue or other Health Effects from Space Radiation

Space radiation exposure may result in degenerative tissue diseases (non-cancer or non-CNS) such as cardiac, circulatory, or digestive diseases, and cataracts. Hereditary risks to the first and subsequent generations of crew off-spring also are a concern. The mechanisms and the magnitude of influence of radiation leading to these diseases are not well characterized. Radiation can cause increased molecular, cellular, and ultimately tissue damage, which may lead to acute or chronic disease of susceptible organ tissues. Data specific to the spaceflight environment must be compiled using appropriate cell culture and small animal models and an approach to extrapolate this data to humans developed in order to quantify the magnitude of this risk to determine if additional protection strategies are required.

1.4 Acute Radiation Risks from Space Radiation

Radiation and synergistic effects of radiation may place the crew at significant risk for acute radiation sickness including prodromal risks, significant skin injury as well as death from a major solar event (SPE) or combined SPE and galactic cosmic rays, such that the mission or crew survival may be placed in jeopardy. Crew health and performance may be impacted by a large SPE or the cumulative effect of GCR and SPEs. Beyond Low Earth Orbit, the protection of the Earth's magnetic field is no longer available, such that increased shielding and protective mechanisms are necessary in order to prevent acute radiation sickness and impacts to mission success or crew survival. The primary data available at present are derived from analysis of medical patients and persons accidentally exposed to high doses of radiation. Data more specific to the spaceflight environment must be compiled to quantify the magnitude of increase of this risk and to develop appropriate protection strategies.

2.0 Operational Relevance Assessment and Recommendations

Permissible exposure limits (PEL) for each space radiation risk limit prevent acute risks (sickness, death or significant loss of function) and limit the risks of late effects such as cancer and degenerative risks to the heart or CNS. The PEL's protect against the upper 95% percent confidence level in the career radiation limits because the uncertainties in risk projection models are significant (>4-fold) such that the use of a median risk estimate could greatly over-estimate or under-estimate the actual risk to crews.

Mission, vehicle, and crew selection requirements are outcomes of the Space Radiation PELs, including requirements on vehicle design and mass, mission duration, and age, gender, or past mission history on crew selection. Current estimates of limitation on mission duration that result from cancer fatality risks alone are shown in Table 1. Table I also shows estimates made in 2001 without the benefit of the most recent research knowledge.

Age, yr	Females		Males	
	Previous (2001) days	Current (2006) days	Previous (2001) days	Current (2006) days
30	54	112	91	142
35	62	132	104	166
40	73	150	122	186
45	89	182	148	224
50	115	224	191	273

Table 1. Increasing safe days in space with reduction in uncertainties.

Research to reduce uncertainties in risk projection models are expected to increase NASA's ability to select crew, extend mission duration, and reduce cost through possible reductions in shielding requirements. Improved knowledge of dose-rate and radiation effects will allow for EVA time lines to be extended in deep space and on the lunar or Mars surface. Furthermore, research approaches that narrow uncertainties in risk models will nodoubt evolve into countermeasure discovery and validation approaches that have large benefits on crew members.

The operational relevance of the research is further described by the following formal objectives as documented in the HRP Program Requirements Document:

Objective 1: Enable the development and validation of NASA's health, medical, and human performance

standards in time for Exploration mission planning & design

Trace: HRP PRD (HRP-47052) Section 4.1

Objective 2: Quantify the human health & performance risks associated with human spaceflight or

Exploration missions

Trace: HRP PRD (HRP-47052) Section 5.1

Objective 3: Develop countermeasures & technologies to prevent or mitigate adverse outcomes of human

health & performance risks

Trace: HRP PRD (HRP-47052) Section 5.2

Objective 4: Develop countermeasures & technologies to monitor and treat adverse outcomes of human

health & performance risks

Trace: HRP PRD (HRP-47052) Section 5.3

Objective 5: Ensure that project processes & products comply with NASA policy directives & NASA

procedural requirements

Trace: HRP PRD (HRP-47052) Section 6.3

3.0 Gaps, Mitigation, Deliverables, Platforms, and Responsibility

The following gaps associated with the 4 major Space Radiation risks are a culmination of gaps identified through the Bioastronautics Roadmap Development, National Academy of Science - Institute of Medicine Review, National Council for Radiation Protection Reviews, Recommendations and Reports, Radiation Discipline Working Group advisory panel recommendations, annual Radiation PI workshops, and the Sept '06 Discipline Review. Note that timeframes/schedules associated with implementation of this Research Plan are found in Appendix A.

3.1. Radiation Carcinogenesis

3.1.1 Priority

3.1.2.1 Lunar Outpost Mission (Priority Level I)

Important: This risk is accepted on current ISS missions. Lunar mission length is similar, but the mission is outside the protection of LEO. Risk still has significant uncertainty and would have to be reported as a significant contributor to risk of mission

3.1.2.2 Mars Mission (Priority Level I)

Important: This risk has considerable uncertainty associated with it, and would need to be reported as a significant contributor to the risk to a Mars mission without tightening the uncertainty bands.

3.1.2 Gaps

Gaps areas are listed in the following Table, and in Gantt chart form illustrating the expected research time-line in Appendix B. A narrative description of the Gaps and Gantt charts are provided below.

- **3.1.2.1:** What are the probabilities for increased carcinogenesis from space radiation as a function of NASA's operational parameters (age at exposure, age, latency, gender, tissue, mission, radiation quality, and dose-rate)?
- **3.1.2.2**: How can tissue specific risk models be developed using human 3D cell culture or animal models for the major cancer sites, including lung, leukemia's, breast, colorectal, stomach, liver, esophageal, skin, brain, and bladder?

- **3.1.2.3:** How can the roles of initiation, promotion, and progression in space radiation carcinogenesis be best determined, and how do they influence the risk projection assumptions such as linearity, additivity, scaling, RBE, and DDREF?
- **3.1.2.4:** How can the mechanisms of cancer risk such as aberrant DNA damage processing, CA, cell cycle, extracellular matrix and growth controls, genomic instability, aberrant signal transduction, epigenetic effects including methylation patterns, persistent oxidative damage, altered senescence, and non-targeted effects be determined? What surrogate endpoints results from this research?
- **3.1.2.5**: How can the projections of tissue specific cancer risk for simulated SPE and GCR be validated using NSRL's EBIS capability?
- **3.1.2.6:** What quantitative procedures or theoretical models are needed to extrapolate molecular, cellular, or animal results to determine the risks of specific cancers in astronauts? How can human epidemiology data best support these procedures or models?
- **3.1.2.7:** How can systems biology approaches be used to integrate research on the molecular, cellular, and tissue mechanisms of radiation damage to improve the prediction of the risk of cancer?
- 3.1.2.8: How can genetic factors that contribute to individual's sensitivity to radiation carcinogenesis be estimated?
- 3.1.2.9: How can epigenetic factor that contribute to individual sensitivity to radiation carcinogenesis be estimated?
- **3.1.2.10:** How can the mechanisms of biomedical countermeasures for space radiation be discovered? Would countermeasures for low-LET radiation have similar efficiency for high-LET radiation?
- **3.1.2.11**: How can 3D cell culture models or animal models developed for space radiation cancer risk determination be extended to validate biomedical or dietary countermeasure approaches to mitigate cancer risk? What testing regime is required at NSRL?
- **3.1.2.12:** What level of cancer risk requires aggressive biomedical countermeasures? And what projection uncertainty in countermeasure effectiveness is required for operational use at NASA?
- **3.1.2.13:** How can the Risk Assessment Projects system biology models of cancer risk be used to project the likely effectiveness of specific biological countermeasures?
- **3.1.2.14**: How can 3D cell culture models or animal models developed for space radiation cancer risk determination be extended to be used as a biomarker approach for Exploration missions?
- **3.1.2.15:** Are there significant synergistic effects from other spaceflight factors (microgravity, stress, altered circadian rhythms, changes in immune responses, depressed nutritional, bone loss, etc.) that modify the carcinogenic risk from space radiation?
- **3.1.2.16:** Are space validation experiments needed for verifying knowledge of carcinogenic risks prior to long-term deep space missions, and if so what experiments should be under-taken?
- **3.1.2.17:** What are the most effective shielding approaches to mitigate cancer risks, how do we know, and implement?
- **3.1.2.18:** What level of accuracy is required of NASA's free space environment models and radiation transport codes to accurately describe the radiation environments on the surface of the moon and Mars?
- **3.1.2.19:** What is the most effective approach to use data from robotic Mars probes on the atmospheric, soil, and magnetic properties of the red planet for estimating carcinogenesis risk, and designing effective shielding or biological countermeasures?

3.1.2.20: How can ISS physical and biological dosimetry data be used to validate components of transport codes and cytogenetic damage descriptions for exploration?

3.1.2.21: What are the most effective approaches to integrate radiation shielding analysis codes with collaborative engineering design environments used by spacecraft and planetary habitat design efforts?

3.1.3. Description of Research Approach

3.1.3.1 Overview

Near-term goals for cancer research focus on reducing the uncertainties in risk projections through the development of tissue specific models of cancer risks, the underlying mechanistic understanding of these models, and appropriate data collection at the NSRL. In the long-term extensive validation of these models with mixed radiation fields is envisioned and research on biological countermeasures and biomarkers will be pursued if needed. Research on improving cancer projections has two major emphases: 1) establishing the correctness of the NCRP model and 2) reducing the uncertainties in the coefficients that enter into the cancer projection model. Research on the validity of the NCRP model relies on studies at the NSRL observing qualitative differences in biological damage between HZE nuclei and gamma-rays and the establishment of how these differences relate to cancer risk. This research will form the basis for an approach to modify or replace the NCRP model..

The level of tolerance in projection model uncertainties depends on the acceptable level of mortality risk (3%) and the projection of risk for each class of mission. Cancer projections for 40-yr females on STS, ISS, 180-day lunar, and Mars missions are currently estimated at about 0.01, 0.35, 0.7, and 5%, respectively. Therefore, a much lower tolerance can be accepted for lunar or Mars mission than mission in LEO to assure risk acceptance levels are not exceeded, and more accurate and mechanistic models of risk must be developed for these missions. This constraint leads to a major goal for research approaches followed by SRPE with uncertainties less than 2-fold needed for long-term lunar stays, and less than ±50% for a Mars mission.

In order to understand whether research has achieved the level of tolerance in cancer risk projections required, interactions between risk assessment research and biological mechanisms and data research is needed. The Gantt first chart in Appendix B shows a major decision point in the research plan related to assessment of uncertainty reduction. If sufficient uncertainty reduction is achieved in the near-term, research on biological countermeasures and minor tissue sites is envisioned to occur in 2014 and out.

The Gantt charts in Appendix B describe research products and deliverables that are listed in detail below.

Collaborative research with the DoE Low Dose Research Program is a key component of the SRPE strategy. The DoE program focus is on low LET irradiation; however collaborative grants are selected from proposals that contain one or more Specific Aims addressing NASA interests using the NSRL. This research augments SRPE research with a large number of grants using state-of-the art approaches including genetics, proteomics, and transgenic animal models. The DoE research is an important part of the SRPE goal to identify biomarkers of cancer risk.

3.1.3.2 Biological Mechanisms & Data

The large number of GCR nuclei type, energies, SPE doses and dose-rates, in combination with the multiple tissue and cancer types makes the performance of large scale animal or 3D human cell culture studies of cancer risk at NSRL prohibitive. Therefore a mechanistic approach is needed and has been segmented into major mechanistic research areas (Gaps 3.1.2.3, 3.1.2.4., and 3.1.2.5). These areas may find synergy in the types and

range of biological models employed, however will differ in the complicated hypothesis questions being addressed. Ultimately, mechanistic studies must progress to determine quantitative data sets for estimating probabilities for increase risk of carcinogenesis (Gap 3.1.2.1) that in conjunction with research on Risk Assessment models will be use to extrapolate risks from experimental model to risks in astronauts on specific exploration missions.

There are distinct mechanisms of cancer induction across and within major tissue sites; thus uncertainty reduction requires tissue specific risk estimates (Gap 3.1.2.2). NRA and NSCOR selections focus is on current estimates of major sites for cancer risks, which include lung, breast, colon, stomach, esophagus, the blood system (leukemia's), liver, bladder, skin, and brain. There are differences in radiation sensitivity based on genetic and epigenetic factors (Gaps 3.1.2.8 and 3.1.2.9) and research in these areas aids the development of tissue specific cancer models. Hypothesis directed studies to establish the underlying mechanisms for the risks, and the possibility of synergistic effects with SPE's or other flight factors may also be considered. NRA, NSCOR, or joint DoE-NASA studies in this area will use state-of-the art animal models (including transgenic mice) and genetically engineered human cell culture models to answer a variety of questions related to the Gaps in biological mechanisms. These studies are critical in establishing the level of proof that underlies NASA risk projection models.

As research understanding is improved, extended duration validation studies with a finite number of animal or 3D human cell culture models using mixed fields representing GCR and SPE will be performed at NSRL using the existing exposure cave or potentially a new cave with improved capability for extended duration GCR simulations (3.1.2.5 and 3.1.2.16).

The cancer risk related NSCOR studies are 5-year studies and allow for long-term animal or sequential mechanistic studies with multiple components. The current NSCOR studies may be renewed dependent on progress and review findings.

3.1.3.3 Risk Assessment

The SRPE approach to uncertainty reduction is based on studying the current model NASA uses as model recommended by the NCRP for projecting cancer incidence and mortality risks for space missions. This model employs the double-detriment life table for calculating the risk of radiation induced cancers against the background of cancers in the general population and competing mortality risks. The cancer rate (Hazard function) is the key quantity in the evaluation; representing the probability at a given age and years since exposure of observing a cancer. The NCRP model assumes the cancer incidence or mortality rate is scalable to human epidemiology data for gamma-rays using a linear-energy transfer dependent radiation quality factor, Q(LET), and a dose and dose-rate reduction factor (DDREF). Other assumptions in the model are made with regard to the transfer of risk across populations, the use of average rates for the US population, the age and age-after exposure dependence of risk on radiation quality and dose-rate, etc. These models will be updated as new data from biological mechanism and data are obtained as described by Gap 3.1.2.6.

Systems biology models provide a framework to integrate mechanistic studies of cancer risk across multiple levels of understanding (molecular, cellular, and tissues), and are the most likely approach to replace the NCRP model. Systems biology models are being developed by the Risk Assessment Project and several NSCOR's, and in conjunction with data collection will improve the descriptions of cancer risk and to lay a framework for future biological counter-measure evaluations and biomarker identification (Gap 3.1.2.7).

3.1.3.3 Shielding Physics & Dosimetry

The evaluation of radiation shielding effectiveness for GCR is currently hindered by data on radiation quality effects and the shape of the dose-response curve for cancer induction. However, controlling secondary neutron components through material selections and developing computer tools for shielding evaluations is a near-term focus for spacecraft design applications as carried out by the Design Tools project under Gap 3.1.2.17 and

3.1.2.21. A goal of the Design Tools project is to provide fast and reliable tools for optimization in support of engineering shielding designs. Radiation physics improvements will be developed in support of these analysis efforts (Gap 3.1.2.18) Space radiation dosimetry will be advanced through NSBRI efforts on fast, reliable tissue equivalent or silicon based technologies (Gap 3.1.2.20). SRPE will also support tasks that integrate data from lunar or Martian robotic probes to improve analysis capabilities (Gap 3.1.2.19)

3.1.3.4 Biological Countermeasures

The long-term phase of research will likely involved research on biological counter-measure (BCM) evaluation, however is a lower priority in the current phase of the program for three reasons: 1) The uncertainties in cancer projections prevent the evaluation of the need for BCM. 2) An improved understanding of the mechanisms of cancer risk is needed to be able to extrapolate results from BCM studies in experimental models to astronauts on exploration missions, and 3) identify effective surrogate markers to perform testing of potential BCMs. Research related to Gaps 3.1.2.10, 3.1.2.11, to 3.1.2.12 will evolve from new knowledge gained from biological mechanisms and risk assessment research. Current NRA studies with anti-oxidants and related agents may be expanded to target specific molecular pathways and tissues, which make the largest contribution to cancer risks. Cell and animal models and appropriate endpoints will be identified and combined with new systems biology tools to obtain quantitative projections of BCM effectiveness for astronauts in specific exploration missions.

3.1.4 Activities to mitigate the gaps:

- Peer-reviewed and directed research (in coordination with ops)
- Integration of research results into Risk Assessment Tool / Design Tool

3.1.5 Product/Deliverables/Milestones:

- PI annual/final reports and peer-reviewed journal articles
- Updated R/A Model for lunar missions (Customer SOMD) Sept 2010
 - (will support both short and long mission trade studies prior to SRR)
- Updated Recommendations on Human System Standards and PELs for lunar radiation environment. (Customer OCHMO) Feb 2011
 - (approximately 1 year prior to LSAM SRR)
- Provide scientific basis and recommendations on radiation protection requirements for short duration lunar missions (input to SRR). Customer: Constellation Dec 2011
 - (6 mos prior to LSAM SRR)
- Updated Recommendations on Human System Standards and PELs for lunar radiation environment (Customer OCHMO) Sep 2014
 - (or approximately 1 year prior to LSH SRR)
- Provide scientific basis and recommendations on radiation protection requirements for long duration lunar missions (input to SRR). (Customer: Constellation) June 2014
 - (6 mos prior to LSH SRR)
- Updated Risk Assessment Model for long duration lunar stays (Customer: RHO, SOMD) Sept 2015
 (approx. 12-18 mos. prior to LSH PDR)
- Baseline enhanced computational design tools for vehicle design assessment (Customer SOMD) March 2010
 - (will support both short and long mission trade studies prior to SRR)
- Enhanced Phase C/D Simulation Tool source code and documentation (Customer: SOMD) March 2012
 - (Supports mission ops SRR and PDR)

- Final Validated & Verified Transport code (Phase II completion) 2014 (Customer SRPE R/A and Design Tool)
 - (supports Mars Architecture trade studies and identification pre-cursor needs)
- Countermeasure delivery (Customer SOMD) ~2014 and subsequent years
- Support LAT and MAT as required

3.1.6 Required Platforms:

- NASA Space Radiation Lab (NSRL);
- Mars Robotic Precursor mission/MSL-RAD (Mars2009 & 2017 for solar min)
- ISS (existing nominal ops (MRID) and measurement data) (i.e. NOT research/experimental)

3.1.7 Project/Organization Responsible for Implementation of Activity:

- SRPE
 - Via NRAs, NSCORs, NASA-DoE Collaborative Research

3.2 Acute and Late Risks to the CNS

3.2.1 Priority

3.2.1.1 Lunar Outpost Mission (Priority Level I)

Important: This risk is accepted on current ISS missions. Lunar mission length is similar, but the mission is outside the protection of LEO. Risk still has significant uncertainty and would have to be reported as a significant contributor to risk of mission.

3.2.1.2 Mars Mission (Priority Level I)

Important: This risk has considerable uncertainty associated with it, and would need to be reported as a significant contributor to the risk to a Mars mission without tightening the uncertainty bands.

3.2.2 Gaps

Gaps areas are listed in the following Table, and in Gantt chart form illustrating the expected research time-line in Appendix B. A narrative description of the Gaps and Gantt charts are provided below.

- **3.2.2.1:** Is there a significant probability that space radiation would lead to immediate or acute functional changes in the CNS due to a long-term space mission and if so what are the mechanisms of change? Are there threshold doses for these effects?
- **3.2.2.2:** Is there a significant probability that space radiation exposures would lead to long-term or late degenerative CNS risks if so what are the mechanisms of change?

- **3.2.2.3:** How does individual susceptibility including hereditary pre-disposition (Alzheimer's, Parkinson's, apoE) and prior CNS injury (concussion or other) alter significant CNS risks? Does individual susceptibility modify possible threshold doses for these risks in a significant way?
- **3.2.2.4:** What are the most effective biomedical or dietary countermeasures to mitigate CNS risks? By what mechanisms are the countermeasures likely to work?
- **3.2.2.5:** How can new knowledge and data from molecular, cellular, tissue or animal models of acute CNS risks, including altered motor and cognitive function and behavioral changes be used to provide significant data for estimating estimate space radiation risks to astronauts?
- **3.2.2.6:** How can new knowledge and data from molecular, cellular, tissue or animal models of late CNS risks, including loss of neurons, altered morphology, role of neuronal and non-neuronal cells, integrated cellular responses, and damage to the vasculature, be best used to efficiently and accurately estimate potential risks to astronauts?
- **3.2.2.7:** Does chronic space radiation exposures or SPE exposure result in significantly increased cell death (apoptosis and necrotic) and if so what are the molecular and cellular pathways and, if so are there any functional consequences?
- **3.2.2.8:** What quantitative procedures or theoretical models are needed to extrapolate molecular, cellular, or animal results to predict CNS risks in astronauts? How can human epidemiology data best support these procedures or models?
- **3.2.2.9:** What are the best shielding approaches to protect against CNS risks, and are shielding approaches for CNS and cancer risks synergistic?
- **3.2.2.10:** Are space validation experiments needed for verifying knowledge of CNS risks prior to long-term deep space missions, and if so what experiments should be under-taken?
- **3.2.2.11** Are there significant CNS risks from combined space radiation and other physiological or space flight factors (e.g., bone loss, microgravity, immune-endocrine systems or other)?
- 3.2.2.12: How can the individual's sensitivity to radiation induced CNS damage be estimated?

3.2.3 Description of Research Approach

CNS risks from GCR are a concern due to the possibility of single HZE nuclei traversals causing tissue damage as evidenced by the light-flash phenomenon first observed during the Apollo missions. Also, as survival prognosis for patients irradiated for brain tumor treatment has improved, patients have shown persistent CNS changes at long times after treatment with gamma-rays suggesting a possible CNS risk for a large SPE. Furthermore, animal studies of behavior and performance with HZE radiation suggest detrimental changes may occur during long-term GCR exposures. Currently, there is no projection model for CNS risks of concern to NASA. Research at NSRL is using a variety of animal and cellular models to study the dose and radiation quality dependence of CNS risks. The extrapolation of model data to astronauts will be the major focus of CNS research in the immediate future.

The Gantt charts in Appendix B describe research products and deliverables for the CNS risks that are listed in detail below.

3.2.3.1 Biological Mechanisms & Data

A critical question for the current phase of research is to establish possible threshold doses for specific CNS risks. It is likely that although acute CNS risks occur only above a dose threshold (Gap 3.2.2.1), and that the lifetime risks for CNS diseases, such as Alzheimer's, will have a distinct dose dependence with the additional questions related to latency to disease of primary interest (Gap 3.2.2.2). The values of possible thresholds for CNS risks and knowledge on how to extrapolate possible thresholds to individual astronauts will be a key milestone in the long-term research plan. An important component of this research is to factor the variation of CNS risk with genotype or other CNS injury (Gaps 3.2.2.3 and 3.2.2.12). A variety of mechanisms must be understood including the roles of neurodegeneration, inflammation, micro-vasculature damage, and changes to specific neuron-chemical pathways. These research areas will have overlaps in usage of NSRL, and potential animal or cellular models employed, however individual NRA or NSCOR projects will pursue distinct hypothesis driven research questions leading to distinct endpoints and biological assays. Hypothesis directed studies to establish the underlying mechanisms for the risks (Gap 3.2.2.7), and the possibility of synergistic effects with SPE's or other flight factors will also be considered (Gaps 3.2.2.7 and 3.2.211).

The CNS risk related NSCOR study is a 5-year study allowing for long-term animal or sequential mechanistic studies with multiple components. The current CNS NSCOR may be renewed dependent on progress and review findings.

3.2.3.2 Risk Assessment

Research approaches are establishing the biochemistry of CNS impacts by HZE nuclei. Since projection based on scaling to human data as done for cancer risk is not possible, a systems biology approach for individual CNS risks may be needed to form a basis for animal to human extrapolation, and will rely on understanding of biochemical changes in the CNS caused by space radiation (Gap 3.2.2.5 and 3.2.2.6, and 3.2.2.8). In the long-term research on validation of models may be required (3.2.2.10). This area is under review by the NCRP. Because of the large number of GCR nuclei types and energies, comprehensive studies under mixed-field SPE or GCR simulation conditions for extended time periods (hours to a few weeks) may be needed at NSRL. Extended duration studies will be useful in addressing SRPE gaps in synergistic risks from other spaceflight factors and radiation damage to the CNS.

3.2.3.3 Biological Countermeasures

Biological countermeasure and biomarker research for CNS risks is a lower priority in the near-term research strategy until the nature and magnitude of the CNS risk is more firmly established. Several studies on oxidative damage and anti-oxidants are supported. The future level of need for BCM research will be driven by the levels of risk are determined such risk may be transition to become a major long-term focus. It is expected that the mechanistic understanding acquired from near-term research will set the course for effective countermeasures approaches in the future as needed (Gap 3.2.2.4).

3.2.3.4 Shielding Physics

The development of new biological understanding of CNS risks will determine if shielding protection for CNS is distinct from other shielding approaches to other radiation risks. Preliminary assessments suggest HZE nuclei with Z>10 or slow neutrons may be a higher relative concern for CNS than other risks, and may place more emphasis on shielding these components (Gap 3.2.2.9).

3.2.4 Activity:

- Peer-reviewed and directed research (in coordination with ops)
- Integration of research results into Risk Assessment Tool

3.2.5 Product/Deliverables/Milestones:

- PI annual/final reports and peer-reviewed journal articles
- Updated Recommendations on Human System Standards and PELs for lunar radiation environment.
 (Customer OCHMO) Charter Feb 2011
 - (approximately 1 year prior to LSAM SRR)
- Provide scientific basis and recommendations on radiation protection requirements for short duration lunar missions (input to SRR). Customer: Constellation Dec 2011
 - (~6 mos prior to LSAM SRR)
- Updated Recommendations on Human System Standards and PELs for lunar radiation environment. Sep 2014
 - (~approximately 1 year prior to LSH SRR)
- - (~6 mos prior to LSH SRR)
- Updated Risk Assessment Model for long duration lunar stays (Customer: RHO, SOMD) Sept 2015
 - (~ approx. 12-18 mos. prior to LSH PDR)
- Countermeasure delivery (Customer SOMD) ~2020 and subsequent years

3.2.6 Required Platforms:

NASA Space Radiation Lab (NSRL);

3.2.7 Project/Organization Responsible for Implementation of Activity:

- SRPE
 - Via NRAs, NSCORs, NASA-DoE Collaborative Research

3.3 Degenerative Risks

3.3.1 Priority

3.3.1.1 Lunar Outpost Mission (Priority Level I)

Important: This risk is accepted on current ISS missions. Lunar mission length is similar, but the mission is outside the protection of LEO. Risk still has significant uncertainty and would have to be reported as a significant contributor to risk of mission.

3.3.1.2 Mars Mission (Priority Level I)

Important: This risk has considerable uncertainty associated with it, and would need to be reported as a significant contributor to the risk to a Mars mission without tightening the uncertainty bands.

3.3.2 Gaps

Gaps areas are listed in the following Table, and in Gantt chart form illustrating the expected research time-line in Appendix B. A narrative description of the Gaps and Gantt charts are provided below.

- **3.3.2.1:** What are the probabilities for specific degenerative tissue risks from SPE and GCR as a function of NASA's operational parameters (age at exposure, age and time after exposure, gender, tissue, mission, radiation quality, dose-rate)?
- **3.3.2.2:** How can tissue specific risk models be developed using human 3D cell culture or animal models for the major degenerative tissue sites, including heart, circulatory, endocrine, digestive, lens and other tissue systems?
- **3.3.2.3:** What are the mechanisms of degenerative tissues risks in the heart, circulatory, endocrine, digestive, lens and other tissue systems? What surrogate endpoints do they suggest?
- **3.3.2.4:** What are the progression rates and latency periods for degenerative risks, and how do progression rates depend on age, gender, radiation type, or other physiological or environmental factors
- **3.3.2.5:** How can the projections of tissue specific degenerative risk for simulated SPE and GCR be validated using NSRL's EBIS capability?
- **3.3.2.6:** What quantitative procedures or theoretical models, including systems biology approaches, are needed to extrapolate molecular, cellular, or animal results to predict degenerative tissue risks in astronauts? How can human epidemiology data best support these procedures or models? (e.g. Are there unique degenerative risks that only occur for the high LET components of GCR and SPE (high charge and energy nuclei, proton and helium stoppers, or neutrons) leading to infinite RBE and other difficulties in risk models?)
- **3.3.2.7:** What are the most effective biomedical or dietary countermeasures to degenerative tissue risks? By what mechanisms are the countermeasures likely to work? (post PPBE)
- **3.3.2.8:** Will countermeasures for cancer, CNS, and degenerative risks be additive, synergistic or antagonistic to each risk?
- **3.3.2.9:** Are there significant synergistic effects from other spaceflight factors (microgravity, stress, altered circadian rhythms, changes in immune responses, etc.) that modify the degenerative risk from space radiation?

3.3.3 Description of Research Approach

Cataracts have long been a research focus of SRPE. More recently several epidemiological studies, including results from the atomic-bomb survivors and nuclear reactor workers, have identified a significant risk of stroke and coronary heart disease (CHD) for low LET radiation at doses comparable to those of an extended lunar mission or a Mars mission, or a short-duration lunar mission incurring a large SPE. Because the risk of heart disease is a recent finding, preliminary SRPE studies in these areas are seeking to establish possible distinctions in mechanisms for this risk between protons and HZE nuclei and gamma-rays. Furthermore, SRPE will take advantage of studies supported by the European Union in this area, which is supporting large scale mouse studies of CHD. These studies should present new insights into the nature of the low LET (gamma-ray) risk at low dose-rates comparable to space conditions, and identify appropriate mouse strains to be used in future SRPE studies.

The Gantt charts in Appendix B describe research products and deliverables for the Degenerative Risks that are listed in detail below. Timelines to begin research on BCM for the Degenerative Risks are dependent on

progress in Cancer and CNS research within the current SRPE research prioritization plans, and perhaps on the findings of the initial biological mechanisms research phase of the research plan.

3.3.3.1 Biological Mechanisms & Data

Preliminary assignments of PEL's for Degenerative risks have been assigned based on human epidemiology data for gamma-ray or x-ray irradiation. Cell or animal models of degenerative risks will be developed and applied to determine the mechanisms for degenerative risks and to determine appropriate risk assessment data for models including relative biological effectiveness and dose-rate dependencies for different space radiation ions at NSRL. In the near-term NRA research will support a small number of studies on heart and lens risks. A long term-focus will be to support an NSCOR in this area in 2014 and beyond. As mission duration increases there could be degenerative risks to other tissues related to digestive diseases and pulmonary changes that become a concern. A long-term goal will be to consider such possible changes in animal validation studies made at a possible extended duration GCR facility developed at NSRL in the future. The NASA Study of Cataracts in Astronauts (NASCA) is collecting valuable data on the incidence and progression rates of cataracts in over 230 current or retired astronauts.

3.3.3.2 Risk Assessment

Risk assessment models for cataract risk will be developed (Gap 3.3.2.6) through biophysical models of new or existing radiobiology data. New models for other degenerative risks will be developed after studies of biological mechanism and data research have matured

3.3.3.3 Biological Countermeasures

An increased risk of cataracts associated with low dose space radiation from past NASA Missions has been reported and is being followed up with a clinical study (NASCA) of cataract progression rates in current or retired astronauts. Several NSRL studies of cataract risks are supported to improve the understanding of how proton and HZE nuclei induce cataracts, and to identify possible countermeasure approaches. The NASCA study and NSRL research will be used by the Risk Assessment Project to project cataract risks for specific space missions. Research on BCMs (Gap 3.3.2.7) for other degenerative risks is envisioned after studies of biological mechanism and data research have matured.

3.3.4 Activity:

- Peer-reviewed and directed research
- Integration of research results into Risk Assessment Tool

3.3.5 Product/Deliverables/Milestones:

- PI annual/final reports and peer-reviewed journal articles
- Updated R/A Model for lunar missions. Charter Sept 2010
 - (will support both short and long mission trade studies prior to SRR)
- Updated Recommendations on Human System Standards and PELs for lunar radiation environment. (Customer OCHMO) Charter Feb 2011
 - (~ approximately 1 year prior to LSAM SRR)
- Provide scientific basis and recommendations on radiation protection requirements for short duration lunar missions (input to SRR). Customer: Constellation Dec 2011
 - (~6 mos prior to LSAM SRR)

- Updated Recommendations on Human System Standards and PELs for lunar radiation environment. Sep 2014
 - (~approximately 1 year prior to LSH SRR)
- Provide scientific basis and recommendations on radiation protection requirements for long duration lunar missions (input to SRR). Customer: Constellation June 2014
 - (~6 mos prior to LSH SRR)
- Updated Risk Assessment Model for long duration lunar stays (Customer: RHO, SOMD) Sept 2015
 (~12-18 mos. prior to LSH PDR)
- Countermeasure delivery (Customer SOMD) ~2015 and subsequent years

3.3.6 Required Platforms:

- NASA Space Radiation Lab (NSRL);
- Note: next generation TEPC will require ISS validation 2010-2012 but this phase is NOT part of the SRPE scope – handed off to ops with minimal oversight from SRPE)

3.3.7 Project/Organization Responsible for Implementation of Activity:

- SRPE
 - Via NRAs, NSCORs, NASA-DoE Collaborative Research

3.4 Acute Radiation Syndromes

3.4.1 Priority

3.4.1.1 Lunar Outpost Mission (Priority Level I)

Important: This risk is accepted on current ISS missions. Lunar mission length is similar, but the mission is outside the protection of LEO. Risk still has significant uncertainty and would have to be reported as a significant contributor to risk of mission.

3.4.1.2 Mars Mission (Priority Level I)

Important: This risk has considerable uncertainty associated with it, and would need to be reported as a significant contributor to the risk to a Mars mission without tightening the uncertainty bands.

3.4.2 Gaps

Gaps areas are listed in the following Table, and in Gantt chart form illustrating the expected research time-line in Appendix B. A narrative description of the Gaps and Gantt charts are provided below.

3.4.2.1: What are the probabilities or RBE's for various acute effects from the GCR and SPE's?

3.4.2.2: How can the dose-rate modifying factors for acute risks of concern be determined from experimental model systems?

- **3.4.2.3:** What are the molecular, cellular and tissue mechanisms of acute radiation damage (DNA damage processing, oxidative damage, cell loss through apoptosis or necrosis, cytokine activation, etc.)?
- **3.4.2.4:** What quantitative procedures or theoretical models are needed to extrapolate molecular, cellular, or animal results to predict acute radiation risks in astronauts? How can human epidemiology data best support these procedures or models?
- **3.4.2.5:** Are their synergistic effects arising from other spaceflight factors (microgravity, stress, immune status, bone loss, etc.) that modify acute risks from space radiation including modifying thresholds for such effects? (post PPBE)
- **3.4.2.6:** Does long-term exposure to GCR modify acute doses from a SPE's in relationship to acute radiation syndromes?
- **3.4.2.7** Does immune depression from a high skin dose or loss of granulocytes in the GI-tract impact the risk of significant depletion of the blood system from a SPE?
- **3.4.2.8:** What are the most effective biomedical or dietary countermeasures to mitigate acute radiation risks? By what mechanisms are the countermeasures likely to work? How can the effectiveness of countermeasures developed on Earth be estimated for exposure of astronauts to a large SPE in deep space, or the lunar or Mars surface?
- **3.4.2.9:** What are the optimal SPE alert and dosimetry technologies for EVAs?
- **3.4.2.10:** What are the most effective shielding approaches to mitigate acute radiation risks, how do we know, and implement?
- **3.4.2.11:** What are the probabilities of hereditary, fertility, and sterility effects from space radiation?
- 3.4.2.12: How can probabilities of acute space radiation events be improved?

3.4.3 Description of Research Approach

There are a variety of acute radiation syndromes of concern following a large SPE exposure. Through careful evaluation of SPE frequency and size probabilities, dose-rates, and likely shielding conditions, and dose distribution at specific organs, the SRPE Risk Assessment Project has determined that the likelihood of acute risks IVA is extremely small, however there are scenarios during lunar or trans-lunar or Mars EVA's where acute radiation sickness may occur. Radiation sicknesses, i.e., the prodromal risks, include the risks of nausea, vomiting, diarrhea, and fatigue. These effects are manifested at about 4 to 24 hours post-exposure for exposures at sub-lethal doses with a latency time inversely correlated with dose. Furthermore, albeit the possibility of acute death through the collapse of the blood forming organs (BFO) is negligible, there is a reasonable concern of a compromised immune system due to high skin doses from a SPE leading to burns, which could increase the risk to the BFO.

In the long-term the SRPE will consider research on fertility, sterility, and hereditary risks from space radiation, and may request the NSBRI support these areas because of their unique nature from other risk areas (3.4.2.11).

The Gantt charts in Appendix B describe research products and deliverables for Acute risk research that are listed in detail below.

3.4.3.1 Biological Mechanisms and Data

Research on acute risks related to EVA conditions must factor in the role of dose-rate over an EVA time course, the additional exposure IVA for a terminated EVA, and other spaceflight factors that could modify expected dose response models for acute risks. Animal and cell culture models appropriate for these acute risks will be used in the research to study protons effects at various doses, dose-rates, and proton energies including simulation of solar particle event spectra (Gaps 3.4.2.1 and 3.4.2.2) including mechanistic studies (Gap 3.4.2.3). A research emphasis on the role of the immune system and possible synergistic effects on acute risks are needed (Gaps 3.4.2.4, and 3.4.2.6). This area is under review by the NCRP. Because acute risks are manifested soon after exposure and there is an existing data based on gamma-ray induced risks, the research is expected to be completed in about a 5-year period by the NSBRI team.

3.4.3.2 Risk Assessment

The Risk Assessment Project has developed acute radiation risk models using a logistic scoring approach and is modifying these models to account for proton and secondary radiation biological effectiveness data. These models will be updated with results from the proposed NSBRI research team when available. A graphical user interface (GUI) of the resulting model will be developed and tested for use in an operational setting (Gap 3.4.2.4). Probabilistic models of SPE are being developed by the Risk Assessment project and in coordination with new results from SMD (Gap 3.4.2.12)

3.4.3.3 Shielding Physics & Dosimetry

Optimization of radiation shielding, dosimetry, and alert approaches is supported with operational research in these areas by both SRPE (Design Tools and Risk Assessment Projects) and the NSBRI, and in collaboration with Space Mission Directorate (SMD) Living with the Star Program (Gap 3.4.2.9). The Design Tools project will develop tools to minimize shielding mass during vehicle design, and the Risk Assessment project will develop probabilistic models appropriate for acute risk protection for mission planning purposes. The development of reliable, lightweight EVA dosimetry is a goal of the research (Gap 3.4.2.10).

3.4.3.4 Biological Countermeasures

The important distinctions in the types of biological models, possible BCMs, and exposure conditions between acute, and the risks of cancer, CNS, and degenerative risks suggests a unique approach. Therefore, the SRPE has requested the NSBRI form a focus team in this area. This team will pursue research on the mechanisms of acute radiation risks and possible BCM development. Studies from radiation oncology of anti-nausea drugs will be considered as well as existing drugs used in spaceflight. The role of synergisms of radiation and other space related insults will be an important thrust of this research.

3.4.4 Activity:

- Peer-reviewed and directed research (in coordination with ops)
- Integration of research results into Risk Assessment Tool

3.4.5 Product/Deliverable/ Milestones:

- PI annual/final reports and peer-reviewed journal articles
- Updated R/A Model for lunar missions. (Customer: RHO, SOMD) Sept 2010
 - (will support both short and long mission trade studies prior to SRR)

- Updated Recommendations on Human System Standards and PELs for lunar radiation environment.
 (Customer OCHMO) Charter Feb 2011
 - (~approx. 1 year prior to LSAM SRR)
- Provide scientific basis and recommendations on radiation protection requirements for short duration lunar missions (input to SRR). Customer: Constellation Dec 2011
 - (~ 6 mos prior to LSAM SRR)
- Updated Recommendations on Human System Standards and PELs for lunar radiation environment.
 Sep 2014 (C)
 - (~approximately 1 year prior to LSH SRR)
- Provide scientific basis and recommendations on radiation protection requirements for long duration lunar missions (input to SRR). Customer: Constellation June 2014
 - (~ 6 mos prior to LSH SRR)
- Updated Risk Assessment Model for long duration lunar stays (Customer: RHO, SOMD) Sept 2015
 (~12-18 mos. prior to LSH PDR)
- Baseline enhanced computational design tools for vehicle design assessment. Charter March 2010
 - (will support both short and long mission trade studies prior to SRR)
- Enhanced Phase C/D Simulation Tool source code and documentation (Customer: SOMD)
 CONTROLLED March 2012 (Supports mission ops SRR and PDR)
- Countermeasure delivery (Customer SOMD) ~2014 and subsequent years
- Support delivery of Next Gen TEPC DTO Flight Unit for ISS ~ Jun 2010

3.4.6 Required Platforms:

NASA Space Radiation Lab (NSRL);

3.4.7 Project/Organization Responsible for Implementation of Activity:

- SRPE & NSBRI
 - Via NRAs, NSCORs, NASA-DoE Collaborative Research

4.0 Background

NASA is concerned with the health risks for astronaut exposures to Galactic Cosmic Rays (GCR) and Solar Particle Events (SPE). GCR exposures occur at low fluence rates with each cell being traversed by a proton about every three days, helium nuclei once every few weeks, and high charge and energy (HZE) nuclei about once every few months. These fluence rates correspond to tissue doses or effective dose-rates of about 0.4-0.8 mGy/d and 1-2.5 mSv/d, respectively. SPE's are low to medium energy protons with smaller components of helium and heavy nuclei. SPE dose-rates are variable over the course of a SPE varying between 0-100 mGy/hr inside a vehicle and between 0-500 mGy/hr if an astronaut is exposed during extra-vehicular activity in deep space or on the surface of the moon. SPE dose-rates may also vary several-fold between tissue sites because of the variable energy spectra of the protons or other nuclei.

For the particles composing space radiation, energy deposition is highly localized along the trajectory of each particle with lateral diffusion of energetic electrons (delta-rays) away from the nuclei's path. Delta-rays from HZE nuclei and protons traverse each cell in space about once per day. This high rate of energy deposition per unit length of trajectory is the Linear Energy Transfer (LET). The unit generally used in radiobiology for LET is the kilo-electron volt per micrometer, or keV/µm. The LET of charged particles changes as a function of the particle velocity or kinetic energy. As the velocity (or the energy) of a particle increases, the LET decreases to a minimum near a velocity of approximately 95% of the speed of light; at higher energies the LET increases very slowly. High-energy charged particles lose energy when they traverse any material. As they slow down, the LET increases to a maximum and then very rapidly decreases to zero. The low energy maximum in LET occurs very

close to the point where the charged particle loses its remaining energy and stops. Nuclear fragmentation and other nuclear interactions, including projectile fragmentation of the primary ion and target fragmentation of tissue constituents, occur as ions traverse tissue. For proton and HZE irradiation, target fragmentation, including secondary neutrons, introduces a high LET component into the radiation field.

The understanding of the countermeasures (including shielding) to space radiation risks is hindered at this time because the large uncertainties in risk projection models indicate a lack of mechanistic understanding and data for assessing the need or effectiveness of countermeasures for specific space missions. GCR nuclei of average energy can penetrate a substantial thickness of materials, on the order of 10's to 100's of cm's of water or aluminum. If they suffer nuclear interactions, the lighter secondary products will lose energy at a lower rate, and therefore will be able to penetrate even further. For this reason, it is not possible to provide sufficient material to fully absorb all types of radiation in space. In addition, the relative biological effectiveness (RBE) of radiation will change as a function of depth of penetration, because the composition of the particles changes and because the LET of each particle changes as it loses energy and slows down inside the material. Inaccuracies in risk assessment models prevent the proper evaluation of shielding material selection and reduce the ability of NASA to apply benefit analyses to shielding evaluations. Biological countermeasures including dietary antioxidants are expected to provide risk reduction for low LET radiation delivered at high dose and dose-rate; however their effectiveness at low dose-rates and for high LET radiation is less clear. Understanding the mechanisms of oxidative damage and its possible reduction through the use of anti-oxidants is a goal of space radiation research. Mechanistic studies of possible biochemical routes for countermeasure actions must be combined with approaches to extrapolate model system results to humans for such countermeasures to be used operationally by NASA. For these reasons, NASA's current research program endeavors to establish the scientific basis for the model to human risk extrapolation problem in order to firmly establish the level of need for biological countermeasures and, if needed, to develop methods to properly assess the effectiveness of such countermeasures and their interactions with countermeasures developed for other non-radiation risk areas.

Radiobiological studies have been conducted using x- or gamma-rays as standards of comparison because of the availability of human data for these radiation types. High-LET particles generally require a lower dose than gamma-rays to induce a given observable biological effect. The quantity used to describe this is the Relative Biological Effectiveness (RBE), which is equal to the ratio of the (generally higher) gamma-ray dose to the (generally lower) particle dose resulting in the same endpoint. For a multitude of radiation endpoints, the RBE varies significantly as a function of LET. The RBE peaks in the neighborhood of approximately $100 \text{ keV/}\mu\text{m}$, reflecting the optimal energy deposition in sensitive targets within cells or tissues. The RBE versus LET relation branches for ions with identical LET but distinct charge numbers (or velocity), and ions with smaller charge number have a higher value of RBE's at a fixed value of LET. Above the RBE versus LET peak for a given charge number, the effectiveness for most endpoints again decreases, due to the fact that further energy deposition in the damaged sites is wasted once a particular endpoint has been achieved.

The characterization of radiation quality in terms of RBE is widely used to describe biological response to radiation, but may ignore qualitative differences in biological effects between different types of radiation. RBE is also the basis for the regulatory approach that specifies Quality Factors patterned after the LET dependence of RBE. Nevertheless, it is limited to biological endpoints for which a significant response to gamma-rays can be obtained. When this is not the case, the ensuing very large values of RBE ("infinite RBE") may be due to the lack of efficacy of gamma-rays rather than a particularly effective aspect of the high-LET radiation. For some endpoints in tissue, including carcinogenesis, Excess Relative Risk (ERR) or excess additive risk (EAR) may be used as the basis for comparing risks to spontaneous or gamma-ray risks, and additional information on the time dependence of these quantities may be obtained, which is valuable for risk assessment. For cancer risk projections, mortality or incidence rates are scaled to available human data for low LET radiation using RBE's or excess relative risk or excess additive risk derived from experimental models. The mechanisms and biological effects associated with high-LET radiation also may be different from those attributable to gamma-rays for the same, or similar, macroscopic endpoints. For example, an observation of reduced latency of disease with increasing LET would not be described using RBE values. For these and other reasons, the description of radiation action is not complete without an understanding of the processes leading to an observed result.

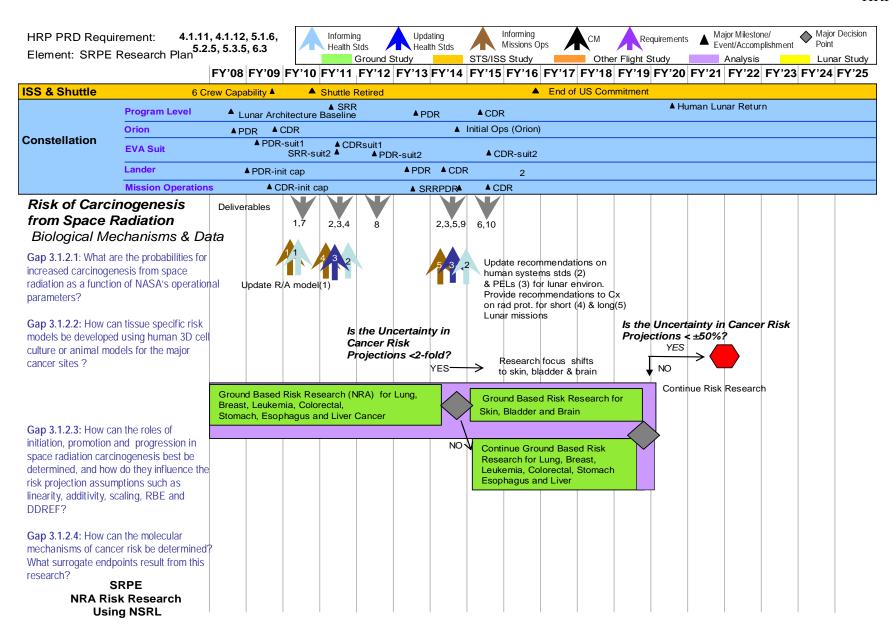
Dose and Dose-rate Reduction Effectiveness Factors (DDREF's) are used to reduce the risk coefficients derived from acute gamma-ray epidemiology data, largely based on the study of the atomic-bomb survivors, to low dose-rate exposure conditions. This approach introduces the uncertainties for gamma-ray exposures at low dose-rates into risk estimates for protons and HZE nuclei. At the present time a universal DDREF value is applied to all solid cancers and a distinct approach used for leukemia's. For large solar particle events intermediate dose-rates are of concern (>50 mGy/hr). The use of the DDREF under these conditions is not warranted and an alternative approach is needed. For potential CNS and degenerative tissue risks, human epidemiology data are limited and new approaches to risk assessment will be needed to provide quantitative risk assessment. NASA is seeking information to determine risk limits for protons and HZE ion induced early or late CNS effects and is imposing conservative CNS limits for lunar missions because of concern for these risks.

Research focus includes: Cancer Risk Estimation including understanding possible differences in the spectrum of tumors induced for low- vs. high-LET radiation and targeted studies on cancers of the GI Tract (colon, stomach); understanding the risk of non-cancer, non-CNS degenerative tissue disease; understanding the dose and dose rate effect for the identified risks; improved methods for extrapolation of cellular and animal mechanisms to human risk; and determining the importance of non-targeted effects especially on spacecraft shielding evaluations. The requirement is to develop an understanding of the mechanisms of radiation damage; increasing the dependency on biological mechanisms and individual genetics, thus reducing dependency on epidemiology data and ultimately reducing the uncertainty in risk projections.

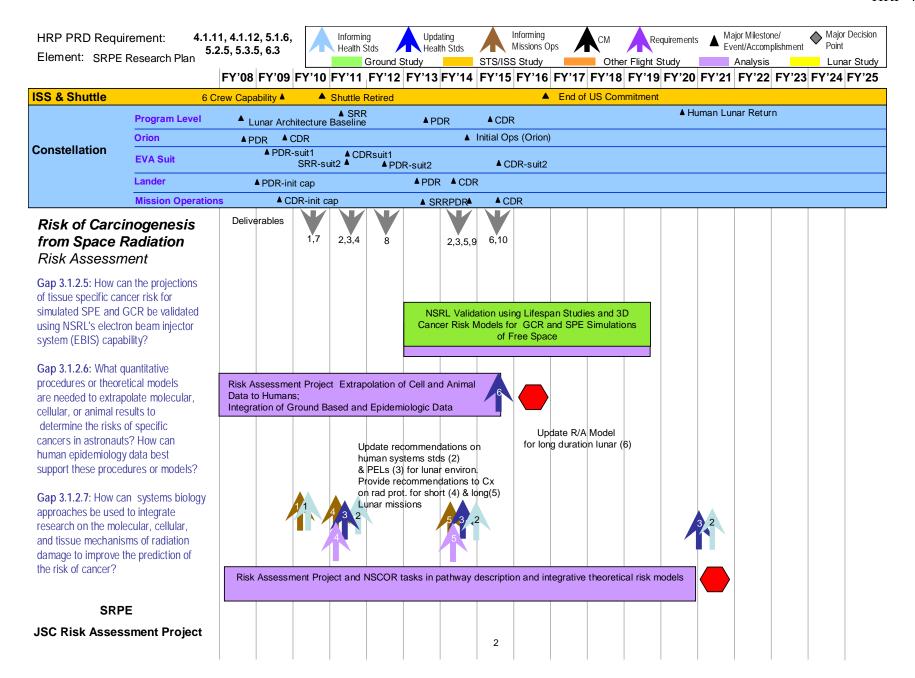
5.0 Acronyms

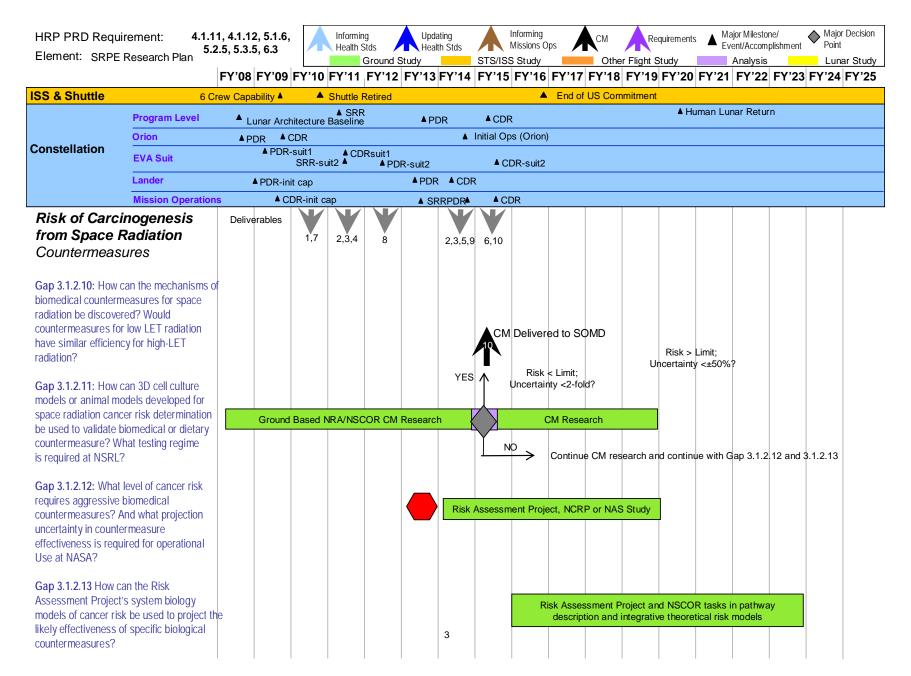
ВСМ	Biological Countermeasure		
BFO	Blood Forming Organs		
СНМО	Chief Health And Medical Officer		
CNS	Central Nervous System		
DDREF	Dose and Dose-Rate Reduction Effectiveness Factor		
DoE	Department of Energy		
EBIS	Electron Beam Injector Source		
ERR	Excess Relative Risk		
GCR	Galactic Cosmic Rays		
HZE	High Charge and Energy		
LAT	Lunar Architecture Team		
LET	Linear Energy Transfer		
MAT	Mars Architecture Team		
NCRP	National Council on Radiation Protection and Measurements		
NRA	NASA Research Announcement		
NRC	National Research Council		
NSCOR	NASA Specialized Center of Research		
NSRL	NASA Space Radiation Laboratory		
PDR	Preliminary Design Review		
RBE	Relative Biological Effectiveness		
SPE	Solar Particle Event		
SRPE	Space Radiation Program Element		

Agency Mission		2006–2013	>	2014–2019	2020–2026	>	Contributions to National Priorities
Lunar Sortie Missions by 2019		Perform research on dose-rate effects of protons, develop shielding design tools; apply probabilistic risk assessment to lunar missions		Validate radiation environment and transport models using lunar data; Validate models of proton dose-rate effects	Develop and deploy operational strategies for managing SPE risks; Apply biomarker methods to samples from lunar crews		Contribute to increased understanding of solar physics; Apply biomarker technologies to problems on Earth
Lunar outpost Missions up to 240 days	-	Use NSRL to simulate space radiation to understand their biological effects; Compete radiation transport codes and design tools		Continue NSRL research on risks; perform research on biological countermeasures; optimize shielding designs for Mars missions	Finish NSRL research on countermeasures; Develop diagnostics of radio-sensitivity and gene therapy for prevention and/or treatment of radiation damage	-	Design exploration missions; Apply new knowledge of radiation effects and NASA computational biology models to human diseases on Earth
Mars Exploration Missions by 2030		New risk model that reduces uncertainties in projections to less than 2-fold; Determine if CNS and degenerative risks from GCR will occur		Revised risk model with uncertainties in risk projections to less than 50%; lunar- instruments to measure Mars surface environment at solar minimum	Apply knowledge on individual risk assessments and biomarkers; integrate accurate long-term solar weather predictions for Mars assessments		Apply countermeasure knowledge to diagnosis, prevention and treatment of diseases on Earth



Graphics

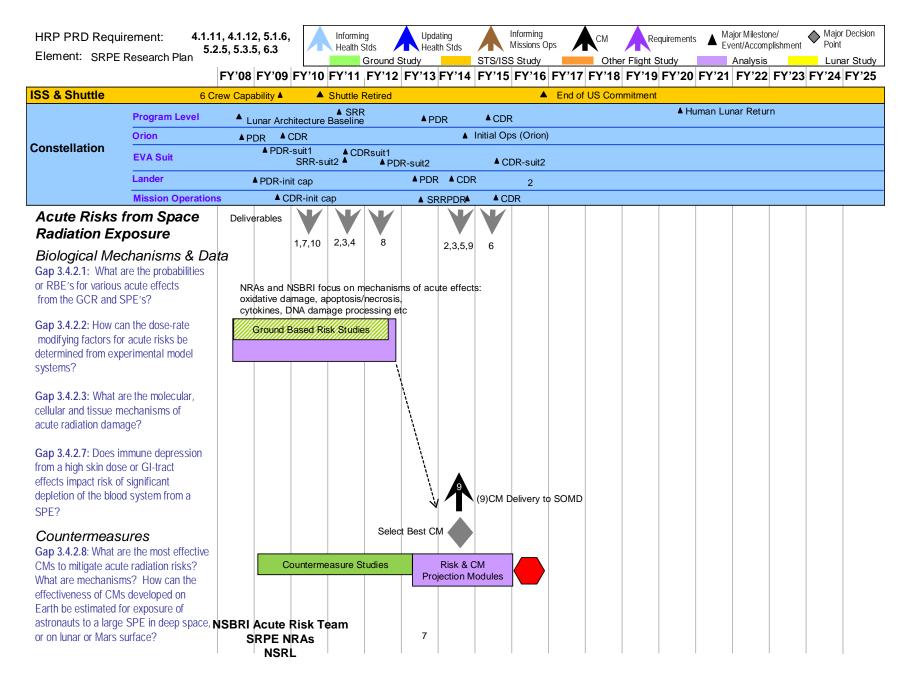


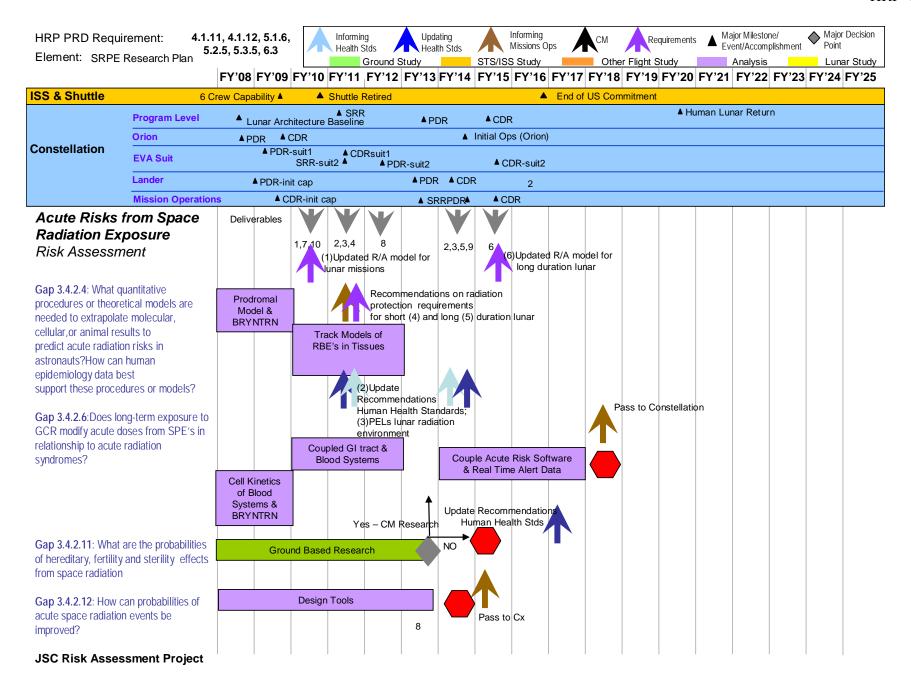


Major Decision Updating Informina Major Milestone/ HRP PRD Requirement: 4.1.11. 4.1.12. 5.1.6. Informing 1 Requirements Missions Ops Event/Accomplishment Health Stds Health Stds 5.2.5, 5.3.5, 6.3 Element: SRPE Research Plan Ground Study STS/ISS Study Other Flight Study FY'08 FY'09 FY'10 FY'11 FY'12 FY'13 FY'14 FY'15 FY'16 FY'17 FY'18 FY'19 FY'20 FY'21 FY'22 FY'23 FY'24 FY'25 **ISS & Shuttle** 6 Crew Capability ▲ ▲ Shuttle Retired ▲ End of US Commitment ▲ Lunar Architecture Baseline ▲ Human Lunar Return **Program Level ▲** CDR **▲** PDR ▲ Initial Ops (Orion) Orion ▲ PDR ▲ CDR Constellation ▲ PDR-suit1 ▲ CDRsuit1 **EVA Suit** SRR-suit2 ▲ ▲ CDR-suit2 ▲ PDR-suit2 Lander ▲ PDR ▲ CDR ▲ PDR-init cap 2 **Mission Operations** ▲ CDR-init cap ▲ SRRPDR▲ **▲** CDR Risk of Acute or Late Deliverables Central Nervous System 1.2.4 Effects from Space Radiation Recommendations on radiation Biological Mechanisms and Data protection requirements for short (3) and long (4) duration lunar mission Gap 3.2.2.1:Is there a significant probability that space radiation would Update Recommendations Human Health Standards (1); lead to acute functional changes in PELs (2) lunar radiation environment the CNS due to a long term space mission and if so what are the Ground Based Risk Research mechanisms? Are there threshold doses for effects? **NSCOR Risk Research** Gap 3.2.2.2: Is there a significant probability that space radiation NO -> Risk Research Gaps 3.2.2.11, 3.2.2.12 synergy with other space flight factors exposures would lead to late Is probability for functional and individual susceptibility degenerative CNS risks, if so what Acute &/or late rad. CNS effects Ψ YES-> CM Research Gap 3.2.2.4 & Risk Research Gaps 3.2.2.11,3.2.2.12 significant? are the mechanisms? Gap 3.2.2.3: How does individual susceptibility alter risk? Does individual susceptibility modify possible threshold doses for risks in a significant way? Gap 3.2.2.7: Does chronic space radiation or SPE exposure result in increased cell death, and if so what are mechanisms and consequences? **NSRL**

Major Decision 4.1.11. 4.1.12. 5.1.6. Updating Informina Major Milestone/ HRP PRD Requirement: Informing Event/Accomplishment Requirements Missions Ops Health Stds Health Stds 5.2.5, 5.3.5, 6.3 Element: SRPE Research Plan Ground Study STS/ISS Study Other Flight Study Analysis FY'08 FY'09 FY'10 FY'11 FY'12 FY'13 FY'14 FY'15 FY'16 FY'17 FY'18 FY'19 FY'20 FY'21 FY'22 FY'23 FY'24 FY'25 **ISS & Shuttle** ▲ End of US Commitment 6 Crew Capability ▲ ▲ Shuttle Retired ▲ SRR Lunar Architecture Baseline ▲ Human Lunar Return **Program Level ▲** PDR **▲** CDR Orion ▲ Initial Ops (Orion) ▲ PDR ▲ CDR Constellation ▲ PDR-suit1 ▲ CDRsuit1 **EVA Suit** ▲ PDR-suit2 SRR-suit2 ▲ ▲ CDR-suit2 Lander ▲ PDR ▲ CDR ▲ PDR-init cap **Mission Operations** ▲ CDR-init cap ▲ CDR ▲ SRRPDR▲ Deliverables Risk of Acute or Late 1,2,3 5 1,2,4 6 Central Nervous System Effects from Space Radiation Update PELs Risk Assessment Flight Data input to R/A Gap 3.3.2.10: Are space validation shielding analysis experiments needed for verifying YEŞ **NCRP** knowledge of CNS risks prior to long-Flight Research Commentary term deep space missions, and if so NO Continue research & what experiments should be under-Input data to CM selection taken? Gap 3.3.2.11: Are there significant CNS Is there synergy of rad. & risks from combined space radiation spaceflight factors for CNS risks? and other physiological or space flight **Ground Based** factors? NRA Research Gap 3.2.2.12: How can the individual's sensitivity to radiation induced CNS NO damage be estimated? Shielding Physics **Ground Based** Gap 3.2.2.9: What are the best NRA Research shielding approaches to protect against CNS risks, and are shielding approaches for CNS and cancer risks synergistic? Risk Assessment Project Shielding Analysis 5

Major Decision Updating Informina Major Milestone/ HRP PRD Requirement: 4.1.11. 4.1.12. 5.1.6. Informina Requirements Missions Ops Event/Accomplishment Health Stds Health Stds 5.2.5, 5.3.5, 6.3 Element: SRPE Research Plan Ground Study STS/ISS Study Other Flight Study Analysis FY'08 FY'09 FY'10 FY'11 FY'12 FY'13 FY'14 FY'15 FY'16 FY'17 FY'18 FY'19 FY'20 FY'21 FY'22 FY'23 FY'24 FY'25 **ISS & Shuttle** 6 Crew Capability ▲ ▲ Shuttle Retired ▲ End of US Commitment ▲ SRR Lunar Architecture Baseline ▲ Human Lunar Return **Program Level ▲** PDR **▲** CDR ▲ Initial Ops (Orion) Orion ▲ PDR ▲ CDR Constellation ▲ PDR-suit1 ▲ CDRsuit1 **EVA Suit** SRR-suit2 ▲ ▲ PDR-suit2 ▲ CDR-suit2 Lander ▲ PDR ▲ CDR ▲ PDR-init cap 2 **Mission Operations** ▲ CDR-init cap ▲ SRRPDR▲ **▲** CDR Risk of Degenerative Deliverables Tissue Effects 2,3,5 2,3,4 Risk Assessment Gap 3.3.2.5: How can the projections of NSRL Validation using lifespan studies and tissue specific degenerative risk for cell /tissue models simulated SPE and GCR be validated using NSRL's EBIS capability? Results from 3.3.2.5 feed into RAP 3.3.2.6 Gap 3.3.2.6: What quantitative procedures or theoretical models Ŵ (6) Updated RA Model Long Lunar Stay R/A Model for Degenerative including systems biology approaches, Risks are needed to extrapolate molecular, Risk Assessment Project Ground and Epidemiology Data Integration for Degenerative Risks cellular, or animal results to predict degenerative tissue risks in astronauts? Countermeasures Gap 3.3.2.7: What are the most effective biomedical or dietary countermeasures to degenerative CM Delivery to Cx (7) tissue risks? By what mechanisms CM & Biomarker Research, Selection & Testing are the countermeasures likely to work? (post PPBE) Gap 3.3.2.8: Will countermeasures for cancer, CNS, and degenerative risks be additive, synergistic or antagonistic to each risk? 6 **SRPE NRA Risk Research** Using NSRL





Major Decision Informing Updating Informing Major Milestone/ HRP PRD Requirement: 4.1.11, 4.1.12, 5.1.6, Requirements Missions Ops Event/Accomplishment Health Stds 5.2.5, 5.3.5, 6.3 Health Stds Element: SRPE Research Plan Ground Study STS/ISS Study Other Flight Study Analysis FY'08 FY'09 FY'10 FY'11 FY'12 FY'13 FY'14 FY'15 FY'16 FY'17 FY'18 FY'19 FY'20 FY'21 FY'22 FY'23 FY'24 FY'25 **ISS & Shuttle** 6 Crew Capability ▲ ▲ Shuttle Retired ▲ End of US Commitment ▲ SRR Lunar Architecture Baseline ▲ Human Lunar Return **Program Level ▲** CDR **▲** PDR Orion ▲ PDR ▲ CDR ▲ Initial Ops (Orion) Constellation ▲ PDR-suit1 ▲ CDRsuit1 **EVA Suit** SRR-suit2 ▲ ▲ CDR-suit2 ▲ PDR-suit2 Lander ▲ PDR ▲ CDR ▲ PDR-init cap **Mission Operations** ▲ CDR-init cap **▲** CDR ▲ SRRPDR▲ Acute Risks from Deliverables Space Radiation Exposure 1,7,10 2,3,4 2,3,5,9 Synergy with Spaceflight Factors Gap 3.4.2.5: Are there synergistic effects CM Research arising from other spaceflight factors that Synergisms with microgravity, stress, modify acute rad risks including modifying immune status, bone loss, etc? Ground-based Analog Studies thresholds for such effects? (post PPBE) & NSRL **NSBRI, SRPE/HRP** Shielding Physics & (7) Comutational Design Tools for Vehicle Design Dosimetry Gap 3.4.2.9: What are the optimal SPE 8)Enhanced Phase C/D Simulation Tool alert and dosimetry technologies for LWS-EMM/REM SMD-LWS Stereo and other missions EVAs? SMD-LWS, NSBRI, SRPE (SBIR) **EVA Dosimetry - NSBRI** Pass to Cx Gap 3.4.2.10: What are the most effective shielding approaches to mitigate acute radiation risks, how do we know, and implement? **JSC Risk Assessment Project**

12.0 RISK OF COMPROMISED EVA PERFORMANCE AND CREW HEALTH DUE TO INADEQUATE EVA SUIT SYSTEMS -I X I

Improperly designed EVA suits can result in the inability of the crew to perform as expected, and can cause mechanical and decompression injury. Suit developers must fully understand the impact of the suit design on crew performance and health to ensure properly designed mobility, pressures, nutrition, life support, etc.

Operational Relevance and Risk Context

Constellation Missions to the Moon and Mars will include frequent EVAs involving exploration, science, construction and maintenance tasks. The effectiveness and success of these missions is dependent on designing EVA systems and protocols which maximize human performance capabilities. It is not be feasible to perform the Constellation EVAs using Apollo suit designs. Limited mobility and dexterity, and high center of gravity and other features of the suit required significant crew compensation to accomplish mission objectives. The Human Research Program has recommended that the EVA Physiology, Systems and Performance Project work with the Constellation EVA Systems Project to develop and execute an integrated human testing program across multiple environments to collect the objective data needed to make informed design decisions to create an EVA system that optimizes human health and performance.

Priority

Lunar Outpost Mission: Important to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

EPSP1: What parameters of EVA suit design affect human performance and how can these designs be modified to increase efficiency in crew health and performance?

M5: How will the suit limit the performance of tasks required for Lunar sortie, Lunar outpost and Mars missions?

SM9: Idealize design of EVA suit for optimized surface ambulation characteristics

Activity:

Studies to Examine Factors that may Affect Human Performance While Working in an EVA Suit

Parameters to be examined include: suit weight, mass, center of gravity (CG), pressure, biomechanics and mobility. Studies will be performed in a number of analog environments. Test activities will include characterizations of ambulation and exploration type activities, such as ambulation on level and inclined surfaces, ambulation while carrying a load, rock collection, shoveling, kneeling, recovery from a fall, and simple exploration and construction tasks using hand tools and power tools. Data collected will include metabolic rates, subject anthropometrics, time series motion capture, ground reaction forces, subjective ratings of perceived exertion (RPE) and operator compensation using the modified Cooper-Harper rating scale. Any conditions that result in suit-induced trauma will also be noted.

Data collected in these studies will be used to generate the "Suit Controllability Predictive Algorithm", which is a model that can be used to predict metabolic cost and subjective ratings based on suit characteristics, subject anthropometrics, and operations concepts. This will be used as a design tool to develop suits that increase efficiency in crew health and performance.

Product/Deliverables:

Recommendations to EVA Systems Project for suit design requirements (optimal suit weight, mass, CG, pressure, biomechanics, mobility, etc); Suit Controllability Predictive Algorithm; and defined set of standard measures to be used for evaluation of prototype suits

Required Delivery Milestone:

A majority of the studies will be completed by the end of FY09 in order to provide inputs to Suit Configuration 1 (initial capability: launch/abort/entry and microgravity EVA) Interim Design Review (FY09) and Suit Configuration 2 (lunar surface operations) Systems Requirements Review (FY10). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15. Where needed, preliminary data will be used for inputs to Suit Configuration 1 Preliminary Design Review (end of FY08).

Studies to refine requirements for Mars suits will be performed during lunar operations (FY20 and beyond).

Required Platforms:

Lunar analogs such as Partial Gravity Simulator (Pogo), Neutral Buoyancy Laboratory (NBL), parabolic flight, and NASA Extreme Environment Mission Operations (NEEMO); lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EVA Physiology Systems and Performance Project (EPSP) – via directed study; some studies will be in collaboration with Constellation EVA Systems Project Office

Activity:

Human Performance in Suit Prototypes, Qualification Units and Flight Suit Articles

Prototype, qualification unit, and flight article suits will be evaluated per the same set of standard measures used in studies to determine optimal suit weight, mass, CG, pressure, biomechanics and mobility requirements (see above). Evaluations of Suit Configuration 1 may include assessments of human performance during suited intravehicular activities and emergency egress. Evaluations of Suit Configuration 2 will include short tests of individual exploration activities, similar to studies described above. In addition, long-term testing of operational concepts will be conducted to determine how the suits affect human performance over the duration of a planned mission. Evaluation of the suit prototypes is expected to be an iterative process with results being used to provide recommendations for multiple subsequent design updates.

Follow-on flight validation and optimization studies with flight suits will occur during lunar surface operations.

Product/Deliverables:

Evaluation of prototype, qualification unit and flight article suits per standard measures with inputs to design updates as needed.

Required Delivery Milestone:

Suit Configuration 1 development and qualification testing will be complete by the System Acceptance Review in 2012. Suit Configuration 2 development and qualification testing will be complete by the System Acceptance Review in 2017. Evaluation of flight article suits will occur during lunar surface operations.

Required Platforms:

Lunar analogs such as Partial Gravity Simulator (Pogo) and parabolic flight; lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Constellation EVA Systems Project Office – via directed study

EPSP3: What are the metabolic costs and ground reaction force (GRF) doses associated with EVA tasks in Lunar sortie, Lunar outpost and Mars missions?

M4: What are the physiological costs of tasks required for Lunar sortie, Lunar outpost and Mars missions?

Activity:

Determine Metabolic Costs and Ground Reaction Forces

Conduct a series of studies to quantify metabolic load and ground reaction forces based on varying subject weight, suit inertial mass, suit pressure and location of center of gravity (CG). Studies will be conducted in several analog environments. Test activities will include a range of lunar surface EVA tasks: ambulation on level and inclined surfaces, ambulation while carrying loads, and exploration type activities such as shoveling, collecting rock samples, and performing construction tasks. Where possible, data will be collected during studies performed to address EPSP1 (see above). Additional studies will be performed to collect 1G baseline data, such as determining the metabolic rates of geological tasks conducted in field studies and the metabolic rate during 10K walk-back over terrain.

Product/Deliverables:

Metabolic costs and ground reaction forces associated with EVA tasks

Required Delivery Milestone:

A majority of the studies will be complete by the end of FY09. This is an internal milestone, since these studies provide data needed to address the following gaps: EPSP2, EPSP4, EPSP5, and B13.

Required Platforms:

Lunar analogs such as Partial Gravity Simulator (Pogo), Neutral Buoyancy Laboratory (NBL), Haughton Mars Project (HMP) and Desert Research and Technology Studies (D-RATS)

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

EPSP4: What are the quantities of consumables required to support EVA in Lunar sortie, Lunar outpost and Mars missions? How can these consumables be managed best?

Activities:

Determine Mission Metabolic Profiles and Perform Evaluations to Optimize Consumable Usage

Project metabolic loads and determine mission metabolic profiles based on operational concepts provided by Constellation Program and/or Lunar Architecture Team (LAT). Profiles will be created for suited intravehicular operations and surface EVA tasks. Metabolic data collected in EPSP1 and EPSP3 studies will be used, and studies will be performed as needed to collect additional metabolic data. Metabolic profiles will be analyzed to determine consumables quantities needed to support mission operations.

Studies and analyses will be performed to develop recommendations for suit design and operational concepts that will optimize consumable usage/management. For example, an oronasal mask will be evaluated as a solution to minimize consumable usage.

Product/Deliverables:

Mission metabolic profiles; recommendations for consumables requirements; and recommendations for operational concepts regarding consumables usage and management

Required Delivery Milestone:

Preliminary studies and analyses will be completed in FY08 and FY09 to provide inputs to Orion Preliminary Design Review (FY08) and Suit Configuration 1 Preliminary Design Review (FY09). Additional inputs will be provided to Surface Operations and Suit Configuration 2 Systems Requirements Reviews (FY10) and Preliminary Design Reviews (FY12). Additional studies may be performed as operational concepts are updated. Validation studies will be performed during mission operations.

Required Platforms:

Modeling capability, such as MATLAB; lunar analogs such as Partial Gravity Simulator (Pogo), Neutral Buoyancy Laboratory (NBL), Rockpile, and Haughton Mars Project (HMP); and lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

EPSP5: What are the energy/hydration requirements and associated waste management requirements of EVA, and what kind of integrated delivery/management systems can be supported in an EVA suit?

N8: What are the energy/nutrient requirements of EVA? What is the best delivery system for these nutrients?

Activity:

Determine Energy, Nutrient, Hydration and Waste Management Requirements

See Risk Factor of Inadequate Nutrition – Gaps N8 / EPSP5

Activity:

Evaluate Concepts for Nutrient and Water Delivery System

See Risk Factor of Inadequate Nutrition – Gaps N8 / EPSP5

Activity:

Evaluate Nutrient Delivery Systems and Waste Management Systems in Suit

See Risk Factor of Inadequate Nutrition – Gaps N8 / EPSP5

EPSP8: What are the biomedical monitoring requirements of an EVA suit for each phase of Lunar and Mars missions?

Activity:

Evaluate Candidate Biomedical Sensors

Work with flight surgeons and biosensor technology experts to identify biomedical monitoring requirements for suited operations: launch/entry/abort, microgravity EVA, and surface EVA.

Product/Deliverables:

Recommendations for biomedical monitoring requirements

Required Delivery Milestone:

Inputs were provided during FY07 to Level II documentation (Human Systems Integration Requirements document) and EVA Systems Project documentation during the Level III and Level IV Systems Requirements Reviews. Additional inputs will be provided as necessary during EVA Suit Configuration 1 and Configuration 2 Preliminary Design Reviews.

Required Platforms:

Workshops and face-to-face meetings

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

Activity:

Evaluate Integrated Biosensor System

Work with Exploration Medical Capability (ExMC) Project to evaluate candidate biomedical sensors and integrated sensor systems during suit tests at lunar analog environments, such as Partial Gravity Simulator (Pogo), Desert Research and Technology Studies (D-RATS), Haughton Mars Project (HMP) or parabolic flight. Biomedical sensors to be evaluated include non-adhesive electrodes, heart rate sensors, temperature sensors, CO₂ sensors and accelerometers.

Product/Deliverables:

Recommendations for integrated biomedical sensor system concept

Required Delivery Milestone:

A majority of the studies will be completed by the end of FY09 in order to provide inputs to Suit Configuration 1 (initial capability: launch/abort/entry and microgravity EVA) Interim Design Review (FY09) and Suit Configuration 2 (lunar surface operations) Systems Requirements Review (FY10). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15. Where needed, preliminary data will be used for inputs to Suit Configuration 1 Preliminary Design Review (end of FY08).

Required Platforms:

Lunar analog testing environments

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Exploration Medical Capability (ExMC) – via directed study

Activity:

Bioadvisory Algorithm Laptop Demonstrator

Develop bioadvisory algorithm laptop demonstrator that monitors biomedical and suit parameters, calculates metabolic rate, and uses voice recognition capability to interact with the crewmember. The algorithm will be evaluated using data collected during tests conducted for EPSP1 and EPSP3. Additional work will refine the algorithm equations and user notifications.

Product/Deliverables:

Bioadvisory algorithm laptop demonstrator, with equations and logic flowchart describing functions of the algorithm

Required Delivery Milestone:

Work will be completed by the end of FY09 in order to provide inputs to Suit Configuration 2 Systems Requirements Review (FY10). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15.

Required Platforms:

Statistical analysis, data collected during suit tests in EPSP 1, EPSP 3

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

Activity:

Evaluate Integrated Biomedical Sensor System

Evaluate integrated biomedical sensor system in prototype suits, qualification units and flight articles. Validation studies with flight suits will occur during lunar surface operations.

Product/Deliverables:

Evaluation of prototype, qualification unit and flight article suits per standard measures, with inputs to design updates as needed

Required Delivery Milestone:

Suit Configuration 1 development and qualification testing will be complete by the System Acceptance Review in 2012. Suit Configuration 2 development and qualification testing will be complete by the System Acceptance Review in 2017. Evaluation of flight article suits will occur during lunar surface operations.

Required Platforms:

Lunar analogs such as Partial Gravity Simulator (Pogo) and parabolic flight; and lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Constellation EVA Systems Project Office – via directed study

EPSP9: What suit-human biomechanical interaction aspects of the EVA suit design affect protection of crew health, and what design changes or countermeasures can be implemented to protect crew health?

Activity:

Suit-Induced Trauma Data Mining

Perform retrospective study (data-mining) to identify suit-induced trauma that has occurred during NBL training and during flight activities. Create searchable database to track suit injury and populate with historical data. Continue to monitor suit-induced trauma in future Shuttle and ISS training and flight activities and enter cases in database.

Identify suit-induced trauma that occurs during suit development/evaluation tests and concept of operation studies for Exploration missions.

Product/Deliverables:

Suit Injury Database

Required Delivery Milestone:

Phase I of the database will be complete in FY08; implementation of phase II is TBD.

Required Platforms:

Partial Gravity Simulator (Pogo), Neutral Buoyancy Laboratory (NBL), parabolic flight, Shuttle and ISS flights, CEV and Lunar operations

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Space Medicine and EVA Systems Project Office – via directed study

Activity:

Identify Mechanisms of Suit-Induced Injury

Conduct a series of studies to identify mechanism of suit-induced injury. Studies currently in progress include: EMU shoulder harness assessment to investigate shoulder injuries due to limited range of motion, studies to measure fingertip pressure and blood flow while working in suit gloves and to assess role of moisture in fingernail damage sustained while working in suit gloves, and

studies to determine the magnitude of oxidative stress in EVA crewmembers. Additional studies will be performed as necessary if new injuries are encountered during development of Constellation suits.

Product/Deliverables:

Recommendations for suit design to mitigate suit-induced trauma

Required Delivery Milestone:

A majority of the studies will be completed by FY10 in order to provide inputs to Suit Configuration 2 Systems Requirements Review. Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15.

Required Platforms:

Lunar analogs, including Partial Gravity Simulator (Pogo), Neutral Buoyancy Laboratory (NBL), parabolic flight

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

Activity:

Evaluate Suit/Seat Induced Trauma During CEV Landing

Perform modeling to evaluate suit/seat induced trauma during CEV landing, based on data provided by Orion and on data collected in studies performed by EVA Systems Project. Develop concepts for occupant protection during landing.

Product/Deliverables:

Recommendations for suit/seat design to avoid suit-induced trauma

Develop finite element models of bone and soft-tissue injury

Required Delivery Milestone:

Preliminary results will be complete in early FY08 to provide inputs prior to Orion Preliminary Design Review and Suit Configuration 1 Preliminary Design Review. Follow-on studies/analysis will be performed as needed through Suit Configuration 1 Critical Design Review (FY11).

Required Platforms:

Modeling capability

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Constellation EVA Systems Project Office and field technology experts in occupant protection – via directed study

Activity:

Evaluate Suit Trauma Countermeasure Garment Prototypes

Work with materials experts in Crew and Thermal Systems Division to develop concepts and prototype of suit trauma countermeasure garment. Candidate concepts include airbags, strainaligning material and crushable foam. Garment will be evaluated in tests conducted by EVA Systems Project Office to simulate landing loads and during suit tests conducted at Lunar analogs.

Product/Deliverables:

Recommendations for design of countermeasures to mitigate suit-induced trauma

Required Delivery Milestone:

Development and testing of preliminary concept will be complete in FY08 prior to Suit Configuration 1 Preliminary Design Review. Subsequent studies will be performed to evaluate iterations of garment design.

Required Platforms:

Lunar analog testing environments

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Crew and Thermal Systems Division and Constellation EVA Systems Project Office – via directed study

Activity:

Evaluate Suit Trauma Countermeasure Garment

Evaluate suit trauma countermeasures in prototype suits, qualification units and flight articles. Validation studies with flight suits will occur during Lunar surface operations.

Product/Deliverables:

Evaluation of prototype, qualification unit and flight article suits per standard measures, with inputs to design updates as needed

Required Delivery Milestone:

Suit Configuration 1 development and qualification testing will be complete by the System Acceptance Review in 2012. Suit Configuration 2 development and qualification testing will be complete by the System Acceptance Review in 2017. Evaluation of flight article suits will occur during Lunar surface operations.

Required Platforms:

Lunar analogs such as Partial Gravity Simulator (Pogo) and parabolic flight; and Lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Constellation EVA Systems Project Office – via directed study

EPSP10: What are the risks and risk definitions of decompression sickness (DCS)? How can DSC risk be managed?

Activity:

DSC Risk Definition and Planning

Define acceptable DCS risk for different phases of Lunar architecture (e.g. short-duration vs. long-duration missions) based on concept of operations. This activity will include several meetings with external experts to discuss DCS policy and definitions of mission success as well as predictive modeling.

Product/Deliverables:

Inputs to Human Systems Integration Requirements document (CxP70024); Exploration DCS Risk and Contingency Plan

Required Delivery Milestone:

This work will be complete by the end of FY08

Required Platforms:

Statistical analysis and modeling

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

Activity:

Develop Integrated DCS Predictive Model

Develop Integrated DCS Predictive Model, which is a tissue gas bubble dynamics model. The model will incorporate parameters such as: pre-breathe conditions, suit pressure, breathing gas composition, depress/repress rates, and duration of exposure. Data used to develop this model will be provided by numerous EPSP studies.

Utilize model to develop operations concepts to manage DCS risk and contingencies. Operational concepts will be validated during Lunar surface operations

Product/Deliverables:

Integrated DCS Predictive Model

Operational concepts/protocols to manage DCS risk

Required Delivery Milestone:

Concepts of operations will be defined by FY13 to provide inputs to the Mission Operations System Requirements Review. Additional studies and analysis will be performed as needed to provide inputs to subsequent reviews.

Required Platforms:

Statistical analysis and modeling

Lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP - via directed study

Activity:

Develop a Pre-Breathe Protocol

Conduct a series of tests to develop a pre-breathe protocol for Lunar surface operations that minimizes DCS risk while meeting WEI requirements. Initial studies will test accept criteria for worst-case scenario, and will involve a 36-hr saturation protocol. Subsequent studies will utilize an exercise-equivalent saturation protocol to evaluate intermittent recompression. Saturation procedure will be performed again to optimize the pre-breathe protocol and to validate procedures. Operational validation will also be performed during Lunar surface operations.

Product/Deliverables:

Validated pre-breathe protocol

Required Delivery Milestone:

Testing will begin in FY10 and will be complete by FY17 for the Suit Configuration 2 / Surface Ops System Acceptance Review

Required Platforms:

Hypobaric chambers

Lunar surface operation

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

EPSP11: What is the best way to acclimate to slightly hypoxic LSAM and Lunar habitat environments?

Activity:

Evaluate Operational Concepts for Transition to Hypoxic Environment

Conduct studies to evaluate operations concepts and determine how human performance is affected due to transition to hypoxic environment. Concepts will be validated during Lunar surface operations.

Product/Deliverables:

Recommendations for concept of operations to acclimate to LSAM and Lunar habitat environment

Required Delivery Milestone:

Work will be complete by FY17 for the Suit Configuration 2 / Surface Ops System Acceptance Review

Required Platforms:

TBD

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

EPSP13: How can heat rejection/suit cooling capability be improved to enhance contingency responses?

Activity:

Liquid Cooling Garment Studies

Conduct studies to evaluate current US and Russian liquid cooling garments and prototype liquid cooling garments. Evaluations will be conducted during suit tests and in thermal chambers.

Product/Deliverables:

Recommendations for design of liquid cooling garment to improve heat rejection/cooling capability

Required Delivery Milestone:

Preliminary studies will be complete by the end of FY09 in order to provide inputs to Suit Configuration 1 Interim Design Review (FY09) and Suit Configuration 2 Systems Requirements Review (FY10). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15. Where needed, preliminary data will be used for inputs to Suit Configuration 1 Preliminary Design Review (end of FY08).

Required Platforms:

Partial Gravity Simulator (Pogo) and thermal chamber

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

Activity:

Evaluate Liquid Cooling Garment in Prototype Suits, Qualification Units and Flight Articles

Evaluate liquid cooling garment in prototype suits, qualification units and flight articles. Validation studies with flight suits will occur during Lunar surface operations.

Product/Deliverables:

Evaluation of prototype, qualification unit and flight article suits per standard measures, with inputs to design updates as needed

Required Delivery Milestone:

Suit Configuration 1 development and qualification testing will be complete by the System Acceptance Review in 2012. Suit Configuration 2 development and qualification testing will

be complete by the System Acceptance Review in 2017. Evaluation of flight article suits will occur during Lunar surface operations.

Required Platforms:

Lunar analogs such as Partial Gravity Simulator (Pogo) and parabolic flight; and Lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Constellation EVA Systems Project Office – via directed study

EPSP6: What work efficiency indices (WEI) metrics of EVA can be used to measure evolution of EVA systems?

Activity:
EVA Work and Task Efficiency
Total EVA work efficiency index (WEI) is defined as:
EVA Time
(Total suit, airlock prep + prebreathe + airlock depress, repress + post EVA

Current NASA EVA Total WEI is 0.39 – 0.51. Constellation EVA Systems Project documentation contains requirements stating that EVA WEI shall be 3.0. Many factors contribute to WEI, including vehicle systems, suit systems, and operational protocols. EPSP will perform evaluations of WEI based on current knowledge and concepts of operations, and will make recommendations to improve WEI. Studies will include the following: 1.) evaluation of suit components that may improve WEI, such as integrated biosensor systems that are quick don/doff and drink bags that require less preparation time; 2.) development of improved pre-breathe protocols; 3.) studies in Lunar analogs that will evaluate the efficiency of different operations concepts and will measure the trends in WEI over time; 4.) evaluation of suit prototypes and development of operational concepts to meet WEI requirements.

Product/Deliverables:

Recommendations for EVA WEI metrics and methods to improve WEI

Required Delivery Milestone:

Inputs were provided in FY07 to EVA Level III Systems Requirements Review based on studies performed during NASA Extreme Environment Mission Operations (NEEMO) missions. Additional studies will continue through FY17, with inputs to Suit Configuration 2 and Surface Operations design reviews. Follow-on flight validation and optimization studies will occur during Lunar surface operations.

Required Platforms:

Lunar analog testing environments, such as Neutral Buoyancy Laboratory (NBL), NASA Extreme Environment Mission Operations (NEEMO), Desert Research and Technology Study (D-RATS), and Haughton Mars Project (HMP)

Lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP in collaboration with Constellation EVA Systems Project Office – via directed study

EPSP7: What surface ops concepts could maximize human performance of mission tasks as well as protect crew health?

M3: What tasks will be required for Lunar sortie, Lunar outpost and Mars missions?

Activity:

Evaluate Operations Concepts

Conduct studies in Lunar analog environments to evaluate surface operations concepts provided by Constellation and/or Lunar Architecture Team (LAT-2 and follow-on). Flight validation and optimization studies will occur during Lunar surface operations.

Product/Deliverables:

Recommendations for surface operations concepts that will maximize human performance of mission tasks and protect crew health

Required Delivery Milestone:

Studies will be performed through FY17, with inputs to Suit Configuration 2 and Surface Operations design reviews, including Systems Requirements Review (FY10), Preliminary Design Review (FY11), Critical Design Review (FY15), and System Acceptance Review (FY17). Follow-on flight validation and optimization studies will occur during Lunar surface operations.

Required Platforms:

Lunar analog testing environments, such as NASA Extreme Environment Mission Operations (NEEMO), Desert Research and Technology Study (D-RATS), and Haughton Mars Project (HMP); and Lunar surface operations

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

SM8: No functional requirements for lunar and Mars surface ambulation have been devised.

Activity:

Develop Fitness for Duty Standard for Surface EVA

Identify recommended operations concept(s) from EPSP7. Based on tasks included in concept(s), analyze metabolic cost data collected during Exploration Task studies and Lunar Concept of Operations Metabolic Profiles studies. Perform analysis to determine 75% VO2 peak and 75% strength and fitness requirements to create fitness for duty standard.

Product/Deliverables:

Recommendations to fitness for duty standard; and metrics for ability to meet standard

Required Delivery Milestone:

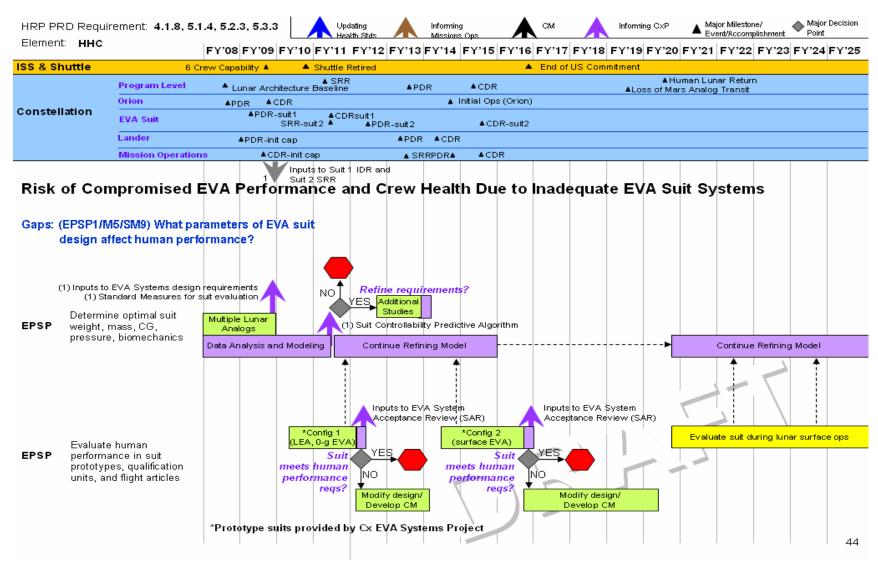
TBD

Required Platforms:

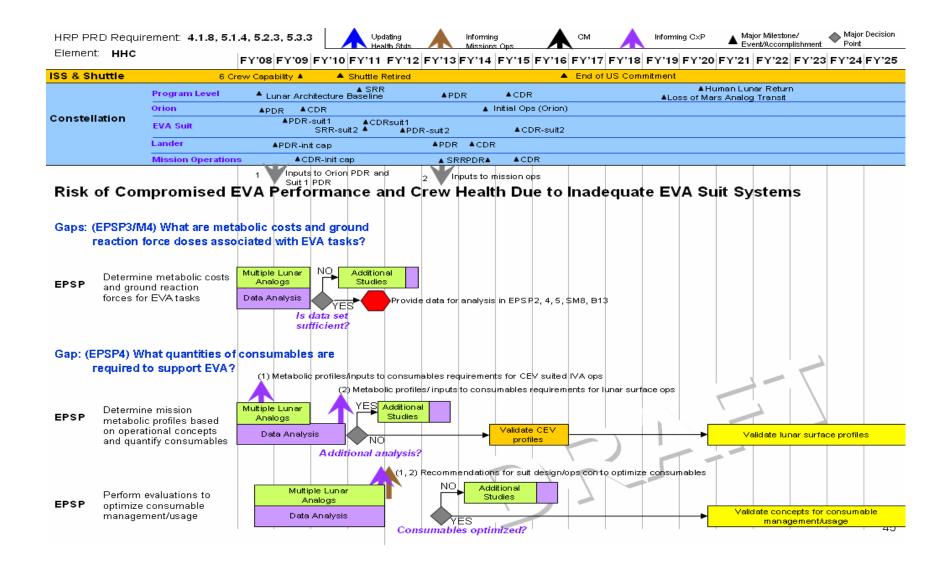
Statistical analysis and modeling capability

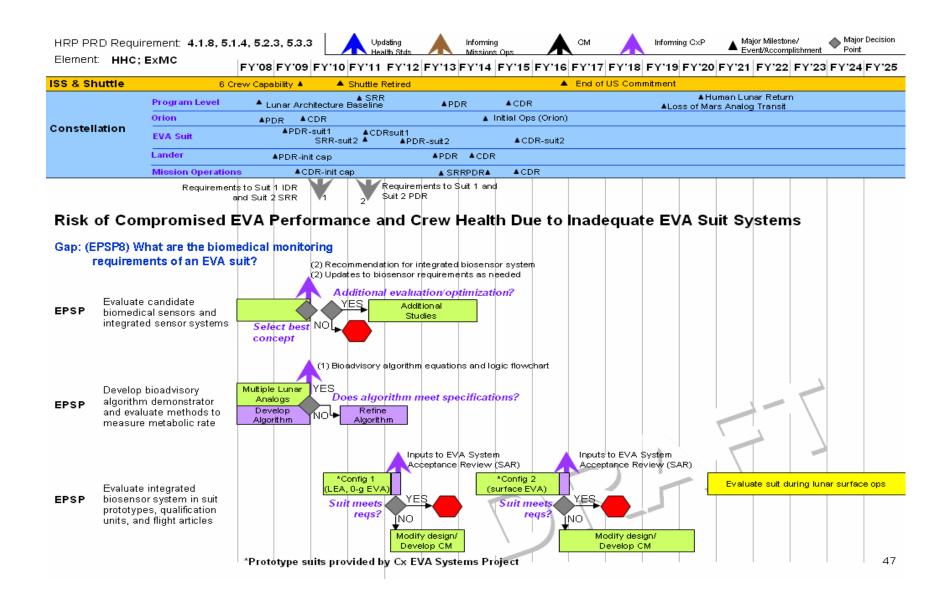
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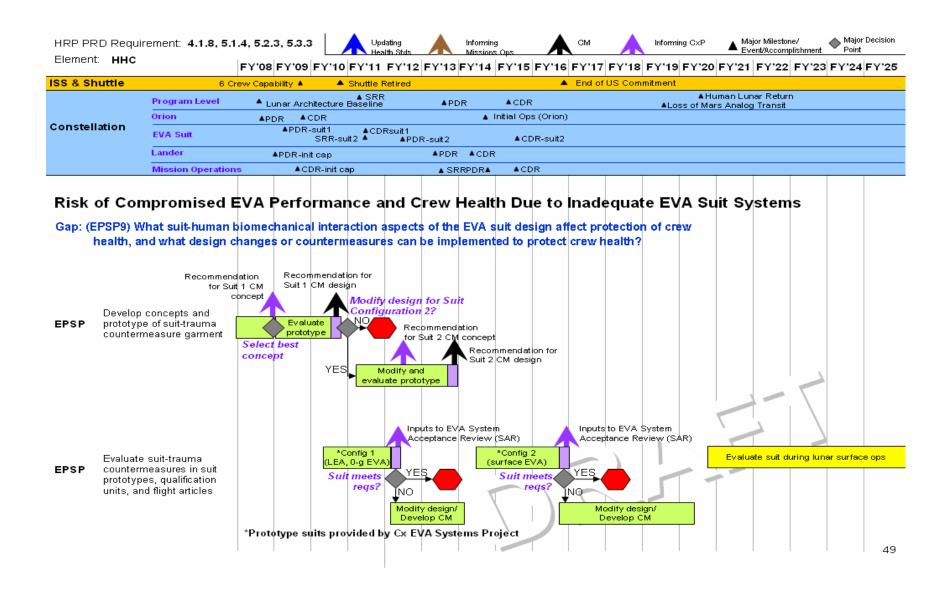
EPSP – via directed study

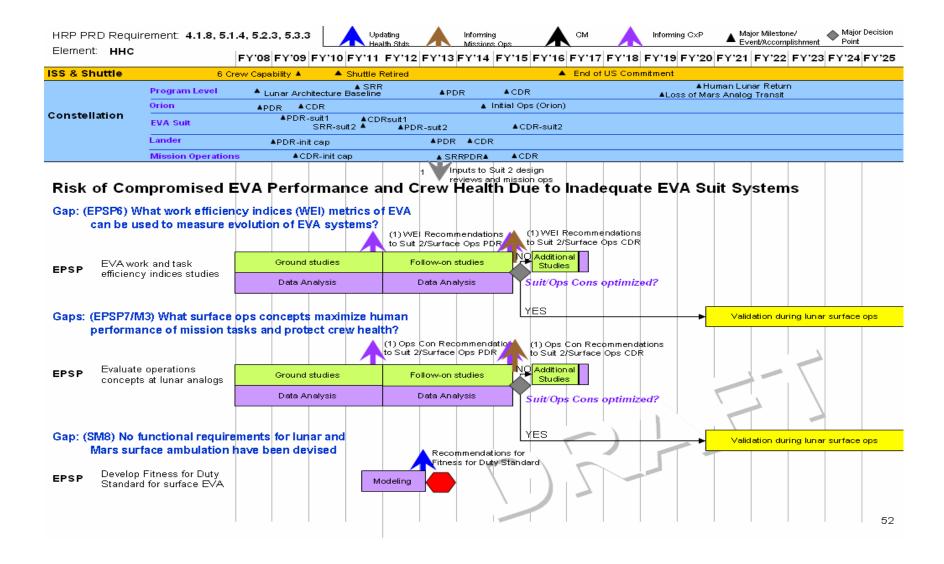


Graphics









HRP-47065

13.0 RISK OF ADVERSE HEALTH EFFECTS FROM LUNAR DUST EXPOSURE -I X N/A

It is clear that prolonged exposure to rock dust is harmful, but it is not clear if exposure to regolith dust is more or less harmful than terrestrial rock dust. Research into this area may determine if exposure limits need be changed, and/or if additional medical treatment capability is required.

Operational Relevance and Risk Context

Lunar dust is characterized as fine, charged and reactive dust capable of entering habitats and vehicle compartments, where it can threaten crewmember health. Testing is critical for the determination of lunar dust toxicity in order to set a permissible exposure limit and risk criteria. Historically, previous lunar regolith studies were limited to gross geological analysis of samples greater than 20 microns and microbial analysis of the regolith. Since that time the science of dust toxicology has emerged (Khan-Mayberry, Noreen N. (JSC-SF) (NASA)) as well as major advances in microscopy, which enable the study of dust samples smaller than 20 microns. Current and future research areas should include identification of lunar dust size, shape and chemistry, the mode of activation and passivation of lunar dust particles, (Khan-Mayberry, Noreen N. (JSC-SF) (NASA)) in vivo and in vitro toxicity (Khan-Mayberry, Noreen N. (JSC-SF) (NASA)) studies of the respiratory system, ocular (Khan-Mayberry, Noreen N. (JSC-SF) (NASA)) toxicity (mechanical and chemical effects), dermal toxicity (Khan-Mayberry, Noreen N. (JSC-SF) (NASA)) (mechanical and chemical effects) and cellular toxicity.

Health effects from chronic exposure to lunar dust may include compromised pulmonary function and possible organ disease through relocation of toxic particulates through the bloodstream. Acute health effects include ocular abrasion which may impair crew vision and dermal abrasion which may compromise function while suited.

The risk of lunar dust exposure was identified during the Apollo missions, when lunar dusts were introduced into the Lunar Lander and command module, resulting in direct exposure and occasional reports of respiratory, dermal and ocular irritation. Current plans for a return to the lunar surface entail an EVA schedule that is extensively more rigorous than that experienced during the Apollo era. Potential exposure of the crew to lunar dust requires that NASA set permissible exposure limits for respirable lunar dust including consideration of dermal and ocular abrasions that may occur during spaceflight. Exposure of the crew to lunar dust can be controlled through operational procedures, such as post EVA clean-up in airlocks, use of temporary breathing apparatus during exposure periods, isolation of contaminated EVA suits and appropriate engineering and design.

Priority

Lunar Outpost Mission: Important to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Not Applicable

Gaps

AEH 1: What are the unique properties of lunar dust that effect physiology?

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Lunar dust particles, unlike most terrestrial dusts, have a high surface area and very distinctive shape characteristics. The respirable fraction of lunar dust has not been characterized. Determining the properties of the respirable fraction is critical for setting health standards.

Activity:

Size, Shape, Chemistry Analysis and Lunar Activation Studies

Perform studies to determine the size distribution, unique shape characteristics and chemical composition of lunar dust particulate. This will facilitate the management of lunar dust particles in the respirable size range. Lunar activation studies will attempt to replicate solar wind, micrometeorite bombardment and lunar processes that cause surface activation of lunar dust. Understanding the activation and passivation processes and their mode of action in the human system will determine potential health effects and exposure limits during mission related tasks.

Product/Deliverables:

These studies will provide activated dust particles for further toxicity testing.

Determination of size distribution factor for calculation of permissible exposure limit.

Required Delivery Milestone:

Provide size distribution factor 2008, Final update 2010

Required Platforms:

The activity will be conducted in various ground laboratory studies

Validation for planetary Ops is required in Lunar Return Timeframe on the Lunar surface.

Project/Organization Responsible for Implementation of Activity:

AEH, LADTAG – via directed study.

AEH 2: What is the toxicity of respired lunar dust in the respiratory system?

During the Apollo missions several crewmembers and at least one Apollo flight surgeon who came in contact with Lunar dust on EVA suits reported respiratory issues with lunar dust. The toxicity data are central in determining a permissible exposure limit and risk criteria for lunar dusts.

Activity:

Inhalation Toxicity testing and Intratracheal Instillation (ITI) Testing of Lunar Dust

These studies will determine the distribution of inhaled and instilled dust particles throughout the lung and the overall toxicity in the lung tissue. Gross pathology will be performed as evidence of the degree of lunar dust toxicity.

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Product/Deliverables:

Data feeds the AEH5 Gap, and are ultimately used to produce an update to the Permissible Exposure Limit for Lunar Dust and subsequently flowed into spacecraft design requirements and operational controls to minimize crew exposure to dust if it is found to be highly toxic.

Required Delivery Milestone:

Provide initial species, dose and activation factors in 2008-09. Finalize factors in 2010.

Required Platforms:

The activity will be conducted in various ground laboratory studies.

Validation for planetary Ops in Lunar Return Timeframe.

Project/Organization Responsible for Implementation of Activity:

AEH, LADTAG – via directed study.

AEH 3: What is the mode of action of lunar dust at the respiratory cellular level?

Respirable particles are suspected to be present on the lunar surface (see AEH Gap 1). To appropriately set accurate exposure limits for crewmembers, it is important to understand the toxicity of lunar dust at the cellular level.

Activity:

Lunar Cell Culture Toxicity Testing

Human lung cell culture will be tested to determine toxicity of lunar dust particles. The generation of reactive oxygen species (ROS) will be one marker of potential toxicity. Active vs. non-active dust will be tested to determine the differences in toxicity due to chemical activation.

Product/Deliverables:

Data will contribute to the determination of both dose and activation factors, and are ultimately integrated and used in gap AEH5 to produce an update to the Permissible Exposure Limit for Lunar Dust and subsequently flowed into spacecraft design requirements and operational controls to minimize crew exposure to dust if it is found to be highly toxic.

Required Delivery Milestone:

Provide required data mid 2008, Final Update 2010.

Required Platforms:

The activity will be conducted in various ground laboratory studies.

Validation for planetary Ops in Lunar Return Timeframe.

Project/Organization Responsible for Implementation of Activity:

AEH, LADTAG – via directed study.

AEH 4: What is the dermal and ocular toxicity of lunar dust?

During Apollo missions several crewmembers reported dermal and ocular issues with lunar dust exposure. Other than these anecdotal reports, there is no objective scientific data to support the dermal and ocular toxicity of lunar dusts. The determination of the dermal and ocular hazards is necessary to predict and prevent any visual decrement and vapor barrier loss during lunar operations.

Activity:

Dermal Toxicity Studies

Dermal abrasion studies will be performed to determine the degree of dermal toxicity from acute and chronic exposure to lunar dust particles.

Product/Deliverables:

Research data indicating the degree of dermal toxicity of lunar dusts; based upon these results a follow on, recommended countermeasures, design and operational controls.

Required Delivery Milestone:

Provide required data in 2009; final recommendations in 2010

Required Platforms:

The activity will be conducted in various ground laboratory studies.

Project/Organization Responsible for Implementation of Activity:

AEH, LADTAG – via directed study.

Activity:

Ocular Toxicity Studies

Ocular exposure studies will be performed to determine the degree of ocular toxicity from acute and chronic exposure to lunar dust particles.

Product/Deliverables

Research data indicating the degree of ocular toxicity of lunar dusts. Based upon these results a follow on could include an ocular exposure standards, recommended countermeasures, design and operational controls.

Required Delivery Milestone:

Provide required data in 2009. Final recommendations in 2010.

Required Platforms:

The activity will be conducted in various ground laboratory studies.

Project/Organization Responsible for Implementation of Activity:

AEH, LADTAG – via directed study

AEH 5: What should be the permissible exposure limits for inhalation of lunar dust?

Activity:

LADTAG final recommendations of Lunar Dust Health Standards

Product/Deliverables:

Reconciliation of extrapolation factors (species, exposure time, activation, size distribution) resulting in recommendations for setting time based (acute and chronic) permissible exposure limits for fresh and aged lunar dust, and subsequent guidelines or requirements for mission planners.

Required Delivery Milestone:

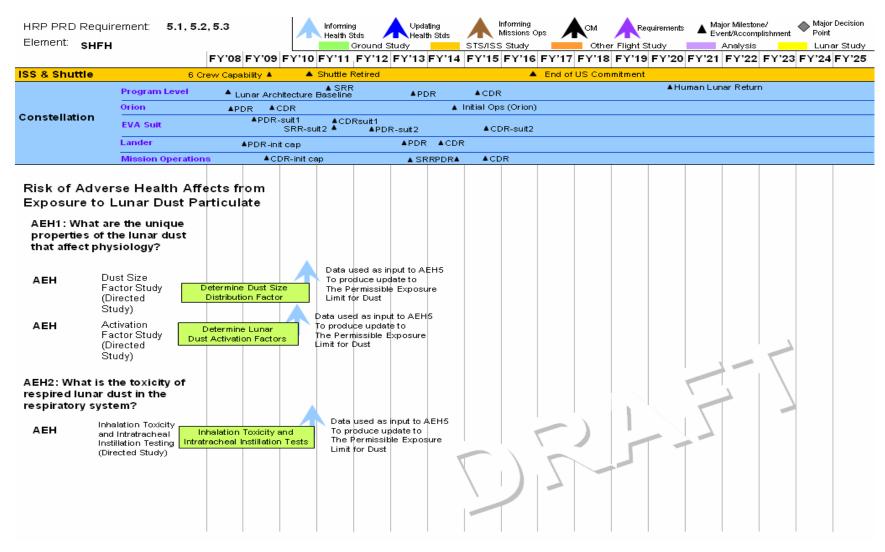
Final recommendations in 2010

Required Platforms:

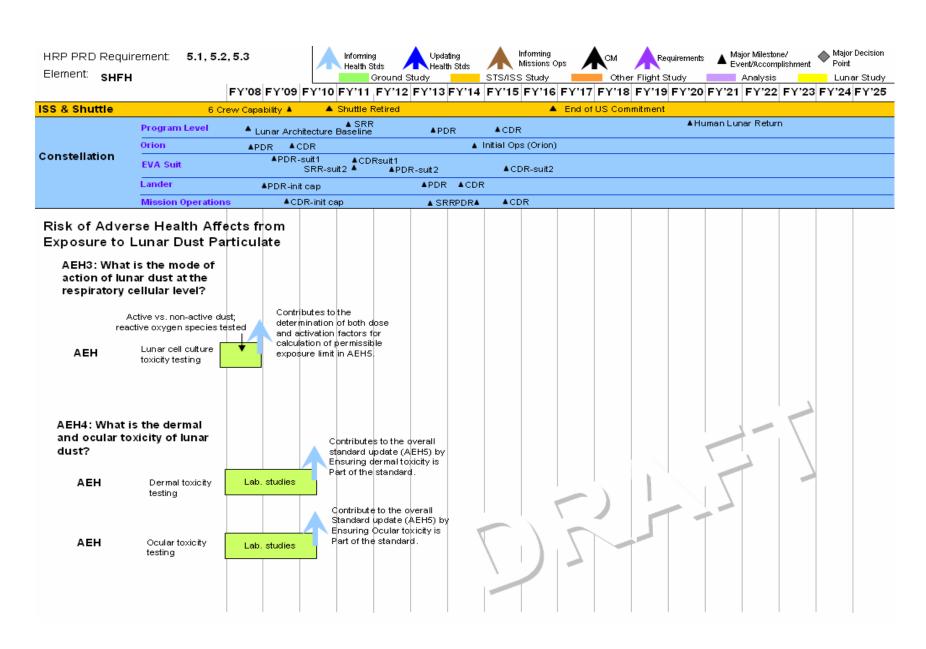
The activity will be conducted in various ground laboratory studies.

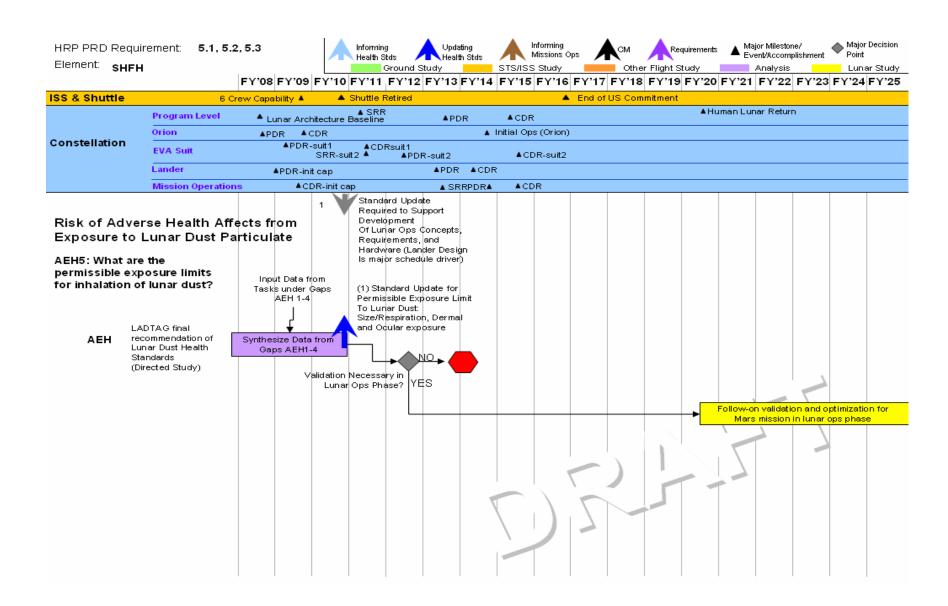
Project/Organization Responsible for Implementation of Activity:

AEH, LADTAG – via directed study.



Graphics





14.0 RISK OF ACCELERATED OSTEOPOROSIS -D X I

Bone mineral loss occurs in microgravity due to unloading of the skeletal system, with average loss rates of approximately 1% per month. It is unclear whether this bone mineral density will stabilize at a lower level, or continue to diminish. It is unknown if fractional gravity, present on the moon and Mars, would mitigate the loss; crewmembers could be at greater risk of osteoporosis-related fractures in later life. Greater understanding of the mechanisms of bone demineralization in microgravity is necessary to frame this risk, as well as to understand how current and future osteoporosis treatments may be employed.

Operational Relevance and Risk Context

It is not currently possible to track the course of changes in bone mineral density and bone quality during long duration missions, or to predict what bone losses will occur during a Mars Mission, or what the risk of fracture will be upon return to Earth after a Mars mission. However, even after 6-month missions there are indications that bone quality/strength does not recover as quickly as bone mineral density. This may represent a long term health effect (accelerated age related osteoporosis or osteopenia and elevated fracture risk) related to this discordant recovery dynamic. This information is required to assess long term health risks to returning crew.

Priorities:

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

B10: What is the time course of bone demineralization during flights >90 days on ISS and during Lunar Outpost missions?

B1: Is bone strength completely recovered with recovery of BMD?

Activity:

Bone Recovery Studies – TBD

Current 2007 NRA solicitation (NNJ07ZSA002N) is requesting research to address the risk of long-term effects on crew health regarding bone loss. There are preliminary indications that overall bone quality/strength does not recover at the same rate that bone mineral density recovers after spaceflight. It is not known if there is a long term health effect related to this discordant recovery dynamic. Research proposals are solicited that directly address this relationship. The specific topic solicited is: novel research that defines the precise relationship between long term recovery of bone mineral density and bone strength/quality, including the effects of multiple spaceflights. It is anticipated that research addressing this topic will require a ground-based or bed rest definition as well as a flight component.

Product/Deliverables:

Space normal data will be gathered to define long term recovery of bone mineral density. In addition, data will be used to validate and/or update the current SFHSS bone standard.

Required Delivery Milestone:

Concurrent flight and ground studies will be performed in 2008-2012 and the results will be utilized to validate and/or update the existing bone health standards in 2013. If results determine that a bone recovery countermeasure is needed, ground-based studies for countermeasure development and follow-on ISS flight validation studies will be solicited. A bone recovery countermeasure will be delivered to mission operations in 2020. These activities are designed to mitigate a risk for long-duration Mars missions and are conducted on board ISS prior to the loss of the ISS as a Mars transit analog. Follow-on validation and optimization studies for Mars missions will occur during lunar ops.

Required Platforms:

ISS is required to gather the space normal data. If the data indicate bone recovery countermeasures are required, follow-on ground-based studies will then be required. The ISS will be required to validate any potential countermeasures. Further validation of the countermeasure for planetary ops will occur in the lunar surface operations timeframe.

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

Activity:

Expanded Analysis of Bone Turnover – study TBD

Current 2007 NRA solicitation (NNJ07ZSA002N) requesting novel technologies that provide for real-time, in-flight monitoring of bone turnover during long-duration spaceflight. It is anticipated that research addressing this topic will require a ground-based or bed rest definition proposal.

Product/Deliverables:

A validated method to analyze bone turnover for use in spaceflight applications is the product to be delivered. If initial studies successfully validate the analysis method(s), follow-on countermeasure development studies may also be performed.

Required Delivery Milestone:

Ground-based studies performed in 2008-2011; flight studies performed in 2011-2014; together with results of technology development, informing mission operations of space normal bone loss rates and updating the SFHSS bone standard in 2015. If all methods and technology results determine that a countermeasure is needed, ground-based studies for countermeasure development and follow-on ISS flight validation studies will be solicited. From these add-on studies, a countermeasure to mitigate the risk will be delivered to mission operations in 2021. These activities are designed to mitigate a risk for long-duration Mars missions and are conducted on board ISS prior to the loss of the ISS as a Mars transit analog.

Required Platforms:

Initially the platform will be ground-based technology development. The ISS may be required to ensure that the instrument or analysis method is appropriate for spaceflight environment.

Project/Organization Responsible for Implementation of Activity:

Non-Exercise Physiological Countermeasures Project (NxPCM) – via NRA

Activity:

Technology to Monitor Bone Quality Changes – study TBD

Current 2007 NRA solicitation (NNJ07ZSA002N) is requesting novel technologies that provide for real-time, in-flight monitoring and/or diagnosis of 1) bone turnover; 2) bone structure; and 3) bone fracture. It is anticipated that research addressing this topic will require a ground-based or bed rest definition proposal.

Product/Deliverables:

A validated method to monitor changes in bone quality for use in spaceflight applications is the product to be delivered. If initial studies successfully validate the analysis method(s), follow-on countermeasure development studies may also be performed.

Required Delivery Milestone:

Ground-based studies performed in 2008-2011; flight studies performed in 2011-2014; together with results of technology development, informing mission operations of space normal bone loss rates and updating the SFHSS bone standard in 2015. If all methods and technology results determine that a countermeasure is needed, ground-based studies for countermeasure development and follow-on ISS flight validation studies will be solicited. From these add-on studies, a countermeasure to mitigate the risk will be delivered to mission operations in 2021. These activities are designed to mitigate a risk for long-duration Mars missions and are conducted on board ISS prior to the loss of the ISS as a Mars transit analog.

Required Platforms:

Initially the platform will be ground-based technology development. The ISS is required to ensure that the instrument is appropriate for spaceflight environment.

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

N5: Can a single test monitor net bone calcium changes?

Activity:

Calcium Isotope Study – TBD

Current 2007 NRA solicitation (NNJ07ZSA002N) requests innovative means to measure and monitor net bone calcium loss during long-duration space flight. It is anticipated that methods for addressing this risk will be among selected proposals.

Product/Deliverables:

A validated method to analyze calcium loss from bone for use in spaceflight applications is the product to be delivered. If initial studies successfully validate the analysis method(s), follow-on countermeasure development studies may also be performed.

Required Delivery Milestone:

Ground-based studies performed in 2008-2011; flight studies performed in 2011-2014; together with results of technology development, informing mission operations of space normal bone loss rates and updating the SFHSS bone standard in 2015. If all methods and technology results determine that a countermeasure is needed, ground-based studies for countermeasure development and follow-on ISS flight validation studies will be solicited. From these add-on studies, a countermeasure to mitigate the risk will be delivered to mission operations in 2021. These activities are designed to mitigate a risk for long-duration Mars missions and are conducted on board ISS prior to the loss of the ISS as a Mars transit analog.

Required Platforms:

Initially the platform will be ground-based technology development. The ISS may be required to ensure that the instrument or analysis method is appropriate for spaceflight environment.

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

B3: What pharmaceuticals against bone loss are best used and how?

MO5: Determine how can osteoporosis treatments be employed?

Activity:

Bisphosphonates as a Countermeasure to Spaceflight-Induced Bone Loss, SMO-021

The purpose of this SMO is to determine whether bisphosphonates, in conjunction with the routine in-flight exercise program, will protect ISS crewmembers from the regional decreases in bone mineral density documented on previous ISS flights. Two dosing regimens will be used: (1) an oral dose of 70 mg of alendronate taken weekly during flight or (2) an I.V. dose of zoledronic acid 4 mg, administered just once approximately 45 days before flight. Secondary goals will be to document the return to normal bone remodeling post-flight in crewmembers who took bisphosphonates. If shown to be an effective countermeasure to spaceflight-induced bone loss, bisphosphonates could prevent or ameliorate several potential bone-related problems. This study is being conducted in conjunction with the Japan Space Agency.

Product/Deliverables:

A product will be an effective pharmaceutical countermeasure to mitigate the risk of bone loss.

Required Delivery Milestone:

The countermeasure will be delivered in 2012.

Required Platforms:

The ISS is required to validate the countermeasure.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

B18: Is vibration a good countermeasure?

Activity:

A Low Intensity Mechanical Countermeasure to Prohibit Osteoporosis in Astronauts During Long-Term Spaceflight; referred to as VIBE (Vibrational Inhibition of Bone Erosion; ISS/HRF Experiment 01-E079).

This study is currently in bed rest trials with projected completion in FY08. This study is currently on hold as a flight experiment on ISS pending the outcome of the ground-based study, having completed an Experimental Requirements Review.

Using 90d of bed rest as a ground-based model of the loss of bone density, reduction in bone strength, and deterioration of postural stability, the principal objectives of this proposal are to establish the ability extremely low-level mechanical vibrations to serve as a countermeasure to curb this loss. Male subjects, between the ages of 25-55, will be recruited for the bed rest study. The bed rest subjects to bear weight in a single leg stance for ten minute periods each day, while subjected to the low level stimulus (30 Hz, 0.3g; n=12), allowing the contralateral limb to serve as an intrasubject control. This will be compared to subjects in single-legged stance who stand on a placebo device (n=12). Evaluation of bone (DXA, QCT and ultrasound), muscle strength, and postural stability will be performed pre- and post bed rest. This work represents a critical step (CRL Level 7) in establishing a physiologically based, non-pharmacologic, non-invasive countermeasure to curb deterioration of the musculoskeletal system, for use on earth or in space.

Product/Deliverables:

Efficacy will be determined as based on the ability of the signal to inhibit bone loss, prevent loss of muscle power and loss of postural stability. Given the ground-based evidence, we anticipate that treated crewmembers will retain bone density and muscle strength regardless of the deleterious consequences of the absence of gravity. Further, it is anticipated that bone loss in the axial skeleton (spine) will be reduced through exposure to the low-level mechanical signal.

Data from these studies is the initial deliverable, and a validated microgravity countermeasure is the product of the ISS study. The ISS flight validation study will inform future lunar bed rest studies using this countermeasure.

Required Delivery Milestone:

Effectiveness of countermeasure in bed rest determined in 2008; delivery of validated microgravity countermeasure in 2014; inform lunar bed rest studies starting in 2020.

Required Platforms:

The bed rest ground analog is required for the demonstration of microgravity countermeasure efficacy, and later for lunar countermeasure efficacy studies. ISS is required as the Mars transit analog for countermeasure validation.

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

Activity

A Low Intensity Mechanical Countermeasure to Prohibit Osteoporosis in Astronauts During Long-Term Spaceflight; referred to as VIBE (Vibrational Inhibition of Bone Erosion; ISS/HRF Experiment 01-E079).

This study is currently on hold as an ISS flight experiment pending the outcome of the ground-based study. The study has completed the Experiment Requirements Review.

If ground-based testing shows positive protection against bone loss, then the subsequent flight study will proceed. During extended missions ISS crewmembers will receive daily doses of high frequency (30Hz), low magnitude mechanical accelerations as tested in ground-based studies.

Assays will evaluate hone density, trabecular and cortical hone density, cortical thickness, appare

frequency (30Hz), low magnitude mechanical accelerations as tested in ground-based studies. Assays will evaluate bone density, trabecular and cortical bone density, cortical thickness, apparent bone quality, and bone mineral density by comparing post-flight DEXA, QCT and ultrasound measurements to pre-flight baseline measurements. Pre- and post-mission muscle strength and postural stability will also be evaluated. Differences from the baseline will be examined in terms of the ability of extremely low-level mechanical stimulation to inhibit the loss of bone quality and quantity. The preservation of muscle strength and postural stability, as based on these mechanical signals will provide a key to the regulatory stimulus in the maintenance of the musculoskeletal system.

Product/Deliverables:

Efficacy will be determined based on the ability of the mechanical signal to inhibit bone loss, prevent loss of muscle power and loss of postural stability.

If the ground-based study results indicate protection from bone loss, a validated microgravity countermeasure is the product of the ISS study. The ISS flight validation study, if performed, will inform future lunar bed rest studies using this countermeasure.

Required Delivery Milestone:

If a countermeasure is determined in the ground-based testing then delivery of validated microgravity countermeasure in 2014; inform lunar bed rest studies starting in 2020.

Required Platforms:

ISS is required for countermeasure validation if bed rest ground analog is validated. If ISS countermeasures are validated and become operational then the bed rest ground analog is required for lunar countermeasure efficacy studies.

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

N14: What nutritional countermeasures can be used to mitigate bone loss?

Activity:

Nutrition Countermeasures for Bone – study TBD

Current 2007 NRA solicitation (NNJ07ZSA002N) requests effective nutritional countermeasures that will assist in maintenance of bone structure and strength during long-duration spaceflight. It is anticipated that research addressing this topic will require bed rest studies.

Product/Deliverables:

Ground-based studies to test proposed countermeasure(s) and ISS studies to validate best countermeasures during in-flight operations. Follow-on validation studies for Mars missions to occur in Lunar ops.

Required Delivery Milestone:

Ground-based studies in 2008-2013; selection of best countermeasures in 2013; flight validation studies in 2013-2016; countermeasure delivery to mission operations by 2016.

Required Platforms:

Ground-based analogs will initially be utilized to develop countermeasures. ISS is required to validate the countermeasures.

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

N7: What are the K+, Mg+, and P+ changes in relation to cardiovascular issues and bone loss?

Activity:

Nutrition Status Assessment – SMO O16E: Nutrition SMO

This is a directed study that seeks to expand the Medical Requirement 016L testing in three ways: 1) include in-flight blood and urine collection, 2) expand nominal testing to include makers of normative markers of nutritional assessment, and 3) add an R+30 session to allow evaluation of post flight nutrition and implications for rehabilitation. Additional markers of bone metabolism (helical peptide, OPG, RANKL, IGF-1) will be measured to better monitor bone health and countermeasure efficacy. New markers of oxidative damage will be measured (8-iso-prostaglandin F2a, protein carbonyls, oxidized and reduced glutathione) to better assess the type of oxidative insults during space flight. The array of nutritional assessment parameters will be expanded to include serum folate, plasma pyridoxal 5'-phosphate, and homocysteine to better understand changes in folate, vitamin B6 status, and related cardiovascular risk factors during and after flight. Additionally, stress hormones and hormones that affect bone and muscle metabolism will be also measured (DHEA, DHEA-S, cortisol, testosterone, estradiol). This additional assessment would allow for better health monitoring, and allow for more accurate recommendations to be made for crew rehabilitation. These additional parameters were added due to the recommendation of an extramural panel that met to define nutritional standards and requirements in 2005. If data indicate countermeasures are necessary for cardiovascular issues and/or bone loss, additional ground-based studies will be initiated. These countermeasures will be validated on board the ISS.

Product/Deliverables:

The SFHSS nutrition standard will be validated/updated and if required, a countermeasure to mitigate the risk of accelerated osteoporosis will be delivered to mission operations.

Required Delivery Milestone:

The SFHSS nutrition standard will be validated/updated in 2011 and countermeasure delivery in 2019.

Required Platforms:

ISS is required to ensure that the data represents space normal and for validation of potential countermeasures. The bed rest ground analog (6° head down tilt) is required for ground studies for countermeasure development.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

Activity:

Lunar Analog Bed Rest Development

This study is for the development of a lunar analog. These lunar mission simulations may or may not include (~3 day) transit phases between Earth and Moon. While it may be useful to simulate some impacts of (7-14 day) sortie missions, the primary focus will be on longer, outpost missions; thus, simulation durations will generally range up to 90 days.

Product/Deliverables:

Lunar analog

Required Delivery Milestone:

The pilot study will occur during 2008 and the completed development of the analog will be completed in 2011.

Required Platforms:

This effort is ground-based analog development, developing a lunar analog model. The model will not be validated until lunar surface mission ops begin the in the 2020 timeframe.

Project/Organization Responsible for Implementation of Activity:

Flight Analogs Project (FAP) – via Directed Study

B14: How does 1/6-g and 3/8-g influence countermeasures?

B17: Can partial gravity be simulated on Earth?

Activity:

Lunar Analog Bed Rest Development

This study is for the development of a bed rest lunar analog. These lunar mission simulations may or may not include (~3 day) transit phases between Earth and Moon. While it may be useful to simulate some impacts of (7-14 day) lunar sortic missions, the primary focus will be on longer, outpost missions; thus, simulation durations will generally range up to 90 days. The timeline for this analog development will be as follows: initially external experts will be consulted to generate ideas for lunar analog development; the pilot study will take place in the spring of FY08; a workshop including external experts will be held post-pilot study; finally a decision on the lunar analog will be made to determine if the analog will be useful.

Product/Deliverables:

Lunar analog

Required Delivery Milestone:

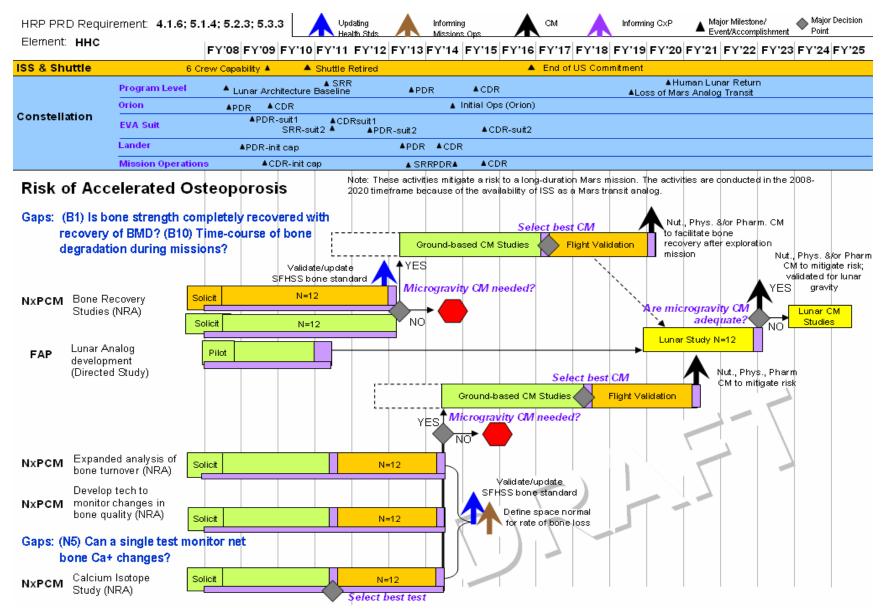
The pilot study will occur during 2008 and the completed development of the analog complete with standard measures data will be completed in 2011. Lunar surface operations will determine if microgravity countermeasures are sufficient for lunar gravity. If additional countermeasures are required, they will be delivered in 2023.

Required Platforms:

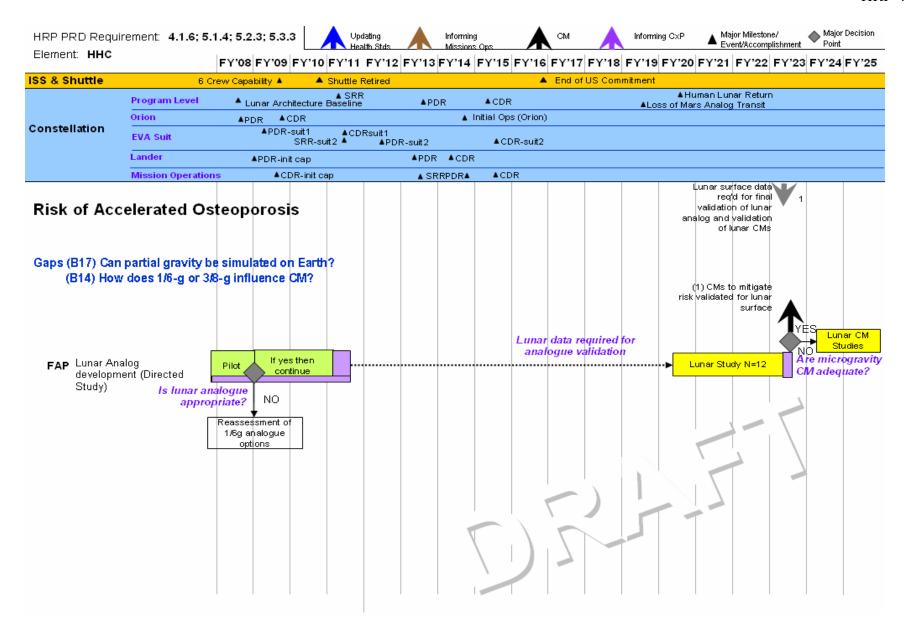
This effort is ground-based analog development, developing a lunar analog model. The model will not be validated until lunar surface mission operations beginning in the 2020 timeframe.

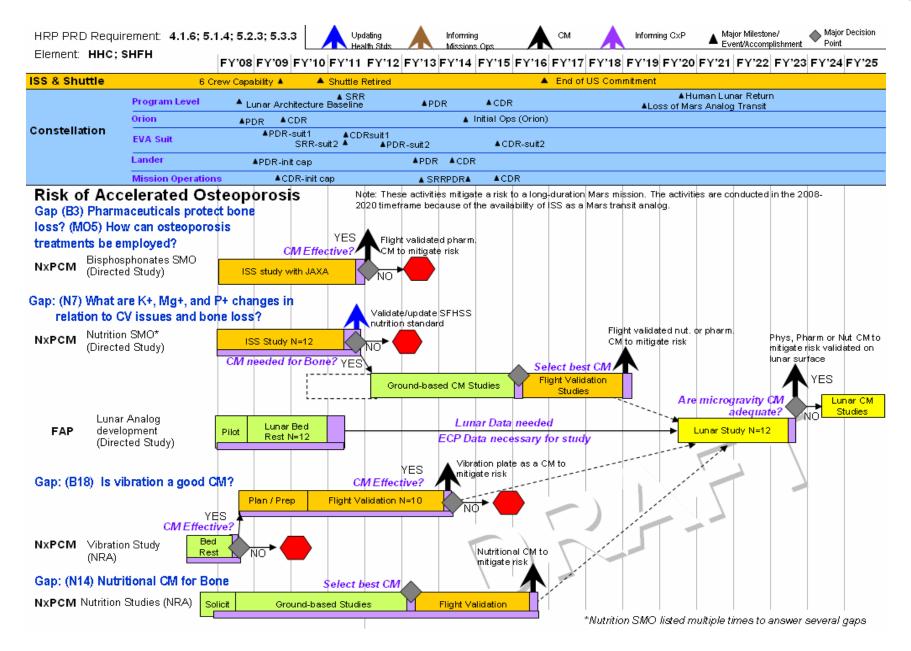
Project/Organization Responsible for Implementation of Activity:

Flight Analogs Project (FAP) - via directed study AP



Graphics





15.0 RISK OF ORTHOSTATIC INTOLERANCE DURING RE-EXPOSURE TO GRAVITY -D X I

Post-flight orthostatic intolerance, the inability to maintain blood pressure while in an upright position, is an established, space-related medical problem. Countermeasures have been successfully identified and implemented (fluid loading, compression garments) or being evaluated (Midodrine & others). Completion of these efforts will be useful in determining what preventive measures should be used to combat orthostatic intolerance during future mission profiles.

Operational Relevance and Risk Context

Twenty percent of Shuttle crewmembers and up to 83% of returning ISS crewmembers suffer hypotension and presyncope or syncope during 10 minutes of upright tilt on landing day. This may constitute a risk when crewmembers experience Earth's gravity after exposure to microgravity. Currently available countermeasures are not effective in all crewmembers; in particular, women are more susceptible than men. While it is well known that crewmembers can be incapacitated by orthostatic intolerance after six-month missions when they return to Earth's gravity, it is not known the degree to which this may be ameliorated in the gravity environment on the Martian surface. Early surface operations may require astronauts to be upright and active soon after landing on Mars. A combination of countermeasures, both physical and pharmaceutical, should be pursued for this risk. It is not known if exposure to 1/6 g and 3/8 g will cause orthostatic intolerance or will have mitigating effects on orthostatic intolerance upon return to 1 g.

Priorities:

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

CV3: Orthostatic intolerance is a potential hazard.

Activity:

<u>Midodrine SMO: Test of Midodrine as a Countermeasure against Postflight Orthostatic Hypotension, SMO-006</u>

To date, available countermeasures (e.g., G-suit, fluid load) have not sufficiently reduced post-flight orthostatic hypotension. This study is designed to evaluate a new pharmacological countermeasure for protection from post-flight orthostatic hypotension. This project will measure the efficacy of Midodrine in reducing the incidence and/or severity of orthostatic hypotension in returning astronauts. Efficacy will be evaluated with an expanded operational tilt test. The tilt test is used to assess the effects of prolonged weightlessness on orthostatic tolerance during upright posture, as measured by supine and standing heart rate, blood pressure, stroke volume, cardiac output and total peripheral resistance.

Product/Deliverables:

Recommendation to Flight Medicine for orthostatic intolerance medication prescriptions

Required Delivery Milestone:

Countermeasure delivery in 2009; countermeasure delivery required to support mission operations by FY13

Required Platforms:

ISS and Shuttle are required for flight validation of the countermeasure.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

Activity:

Hypovolemia Studies

A hypovolemia model that reproduces the plasma volume loss seen on landing day has been developed utilizing a regimen of a single dose of IV furosemide, followed by 36 hours of a very low salt diet. In the astronauts, this dehydration regimen reproduces the landing day incidence of orthostatic hypotension and presyncope during tilt tests with 100% fidelity. Future work will include testing the utility of this ground-based model by expanding the measurements to include specific hemodynamic and vascular responses, and compare/contrast them with measurements from bed rest studies. Additional activities include validating the Jobst stocking as a method to mitigate orthostatic intolerance on landing day, and examining alternate pressure garments if the Jobst stocking is not validated as a valid countermeasure. In addition, alternate medications to mitigate orthostatic intolerance (i.e., octreotide) will be examined using the hypovolemic model. Follow on studies could include validating octreotide in the 6° head-down tilt bed rest model and flight validation of octreotide on ISS. VO2max measurements will also be taken using the hypovolemia model. These data will be combined with the VO2 max SMO occurring on-board the ISS.

Product/Deliverables:

Inform mission operations regarding data gathered from Jobst stocking studies. If additional pressure garments require evaluation, mission operations will be informed of those results. Data from the pressure garments studies and from the VO2max studies will be combined to update the SFHSS cardiovascular standard. If the octreotide pharmaceutical is successful, it will be delivered to mission operations as a validated countermeasure against orthostatic intolerance.

Required Delivery Milestone:

Information on the pressure garments activities will be delivered to mission operations in 2008 and 2010; delivery required in FY08 to support G-suit design requirements. The SFHSS cardiovascular standard will be updated in 2010; delivery required in FY08 to support G-suit design requirements. A validated pharmaceutical countermeasure will be delivered in 2016; delivery required in FY13 to support mission operations requirements.

Required Platforms:

These activities utilize the ground-based hypovolemia model. Future countermeasure evaluation studies will utilize the bed rest analog and countermeasure validation will utilize ISS to ensure proper use in the spaceflight environment.

Project/Organization Responsible for Implementation of Activity:

NxPCM – directed study

Activity:

Gender Differences in Bed Rest: Autonomic and Neuroendocrine Changes and Vascular Responses in Lower and Upper Extremities

Although the reasons are undefined, female astronauts are more susceptible to post-flight orthostatic hypotension and presyncope than male astronauts. Due to the lack of cardiovascular bed rest studies that have female participation, many conclusions about the effects of simulated microgravity on humans may be flawed, in that they fail to describe physiologic mechanisms in women. This study focuses on how differences in strategies of arterial pressure control in men and women affect orthostatic tolerance before and after bed rest. Endothelium-dependent, endotheliumindependent and adrenergic receptor responses in both arteries and veins will be evaluated, before and after bed rest. In addition, plasma volumes, and hemodynamic and neuroendocrine responses to arterial and cardiopulmonary baroreceptor inputs will be measured in women versus men, before and after bed rest. Studies have indicated a differential response of different vascular beds in animal studies where hindlimb-suspended rats show hypertrophic remodeling of the vessels in their forelimbs and atrophic remodeling in the vessels of their hindlimbs. This is thought to occur because changes in transmural pressures and shear forces with hindlimb suspension occur in opposite directions in the upper and lower extremities. These studies have not been repeated in female rats, and nothing like this has been performed in humans of either gender. Since humans are bipedal, bed rest would greatly reduce transmural pressures and shear forces in the legs, but not the arms. If vessel remodeling follows the patterns in humans as in the rats, large changes could occur; this might contribute to orthostatic hypotension after bed rest. Accordingly, the study will repeat the vascular measurements mentioned above in both upper and lower extremities before and after bed rest and relate the findings to the occurrence of orthostatic hypotension.

Product/Deliverables:

The initial product is space normal data on gender differences with regards to orthostatic intolerance. If the results indicate that a gender-specific countermeasure is needed, ground-based countermeasure studies will be solicited. When the development is complete the countermeasure will be validated on the ISS. Data gathered from all activities will be fed into lunar surface studies.

Required Delivery Milestone:

Bed rest study completion in 2012; updates to the cardiovascular standard 2012; ground-based countermeasure studies solicited and performed in 2012-2016; informing mission operations in 2015; flight validation studies in 2016-2019; delivery of validated countermeasure(s) in 2019. All products are needed by FY13 to support mission operations requirements.

Required Platforms:

Initially this study requires the bed rest ground analog to microgravity. If a gender-based countermeasure is indicated, the countermeasure will be evaluated in the bed rest microgravity analog and the countermeasure will be validated for flight using the ISS.

Project/Organization Responsible for Implementation of Activity:

NxPCM - NRA

Activity:

<u>Vestibular-Cerebrovascular Interaction and their Contribution to Post-Spaceflight Orthostatic Intolerance</u>

The goal of this research is to examine the role of vestibular inputs in cerebral blood flow regulation and the effect of these inputs on orthostatic tolerance. The general hypothesis is that otolith mediated vestibular inputs act as a feed forward mechanism causing cerebral vasodilation to compensate for the decrease in cerebral perfusion pressure during the upright posture. The results of these studies will provide direct evidence on the role of vestibular inputs in cerebrovascular regulation. This work may lead to new methods to diagnose and treat post-spaceflight orthostatic intolerance and may have ground based applications as well.

Product/Deliverables:

Study completion, final report of findings

Required Delivery Milestone:

Study completion and final report by 2009

Required Platforms:

Ground-based work

Project/Organization Responsible for Implementation of Activity:

NxPCM - NRA

Activity:

Lunar Analog Bed Rest Development

This study is for the development of a lunar analog. These lunar mission simulations may or may not include (~3 day) transit phases between Earth and Moon. While it may be useful to simulate some impacts of (7-14 day) sortie missions, the primary focus will be on longer, outpost missions; thus, simulation durations will generally range up to 90 days.

Product/Deliverables:

Lunar analog

Required Delivery Milestone:

The pilot study will occur during 2008 and the completed development of the analog will be completed in 2011.

Required Platforms:

This effort is ground-based analog development, developing a lunar analog model. The model will not be validated until lunar surface mission ops begin the in the 2020 timeframe.

Project/Organization Responsible for Implementation of Activity:

FAP – via Directed Study

CV4: Is 1/6-g exposure protective of 1-g orthostatic tolerance?

Activity:

Lunar Analog Bed Rest Development

This study is for the development of a lunar analog. These lunar mission simulations may or may not include (~3 day) transit phases between Earth and Moon. While it may be useful to simulate some impacts of (7-14 day) sortie missions, the primary focus will be on longer, outpost missions; thus, simulation durations will generally range up to 90 days.

Product/Deliverables:

Lunar analog

Required Delivery Milestone:

The pilot study will occur during 2008 and the completed development of the analog will be completed in 2011.

Required Platforms:

This effort is ground-based analog development, developing a lunar analog model. The model will not be validated until lunar surface mission ops begin the in the 2020 timeframe.

Project/Organization Responsible for Implementation of Activity:

Flight Analogs Project (FAP) – via Directed Study

Activity:

Lunar Analog Study TBD

This study will utilize the lunar analog to determine if lunar gravity has any protective effects on orthostatic intolerance. Using the analog, it will be determined if countermeasures to protect against orthostatic intolerance are required for the lunar surface. If countermeasures are required, follow-on countermeasure development studies will be initiated. These countermeasures will be validated on the lunar surface.

Product/Deliverables:

The deliverable will be updates to the SFHSS cardiovascular standard and a validated lunar countermeasure to orthostatic intolerance.

Required Delivery Milestone:

This study requires development of the lunar analog and will occur 2011-2014 with updates to the cardiovascular standard occurring in 2014. These updates are needed by FY13 to support mission operations requirements. If lunar countermeasures are required, those studies will take place in the 2014-2020 timeframe. A lunar surface validated countermeasure will be delivered to mission operations on 2023. The lunar countermeasures are needed by FY14 for lunar mission operations implementation.

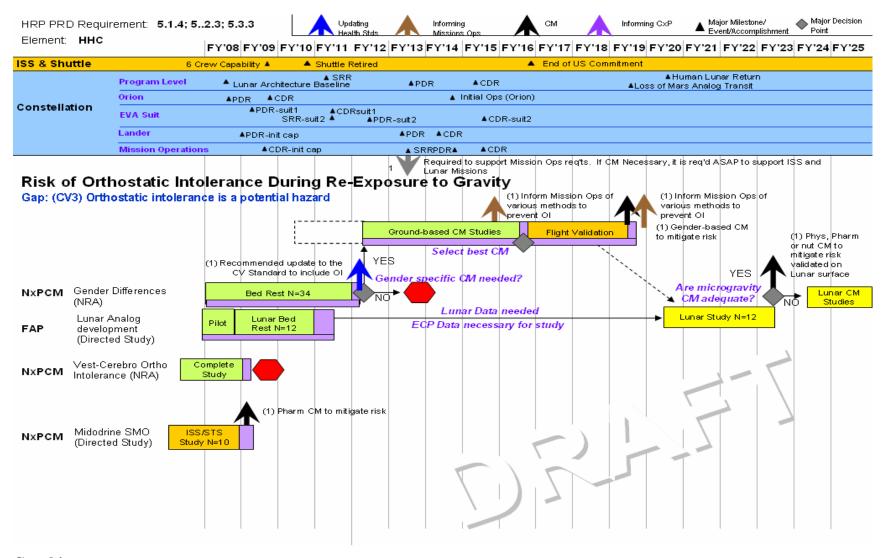
Required Platforms:

This effort requires the lunar analog model. Countermeasure validation requires the lunar surface.

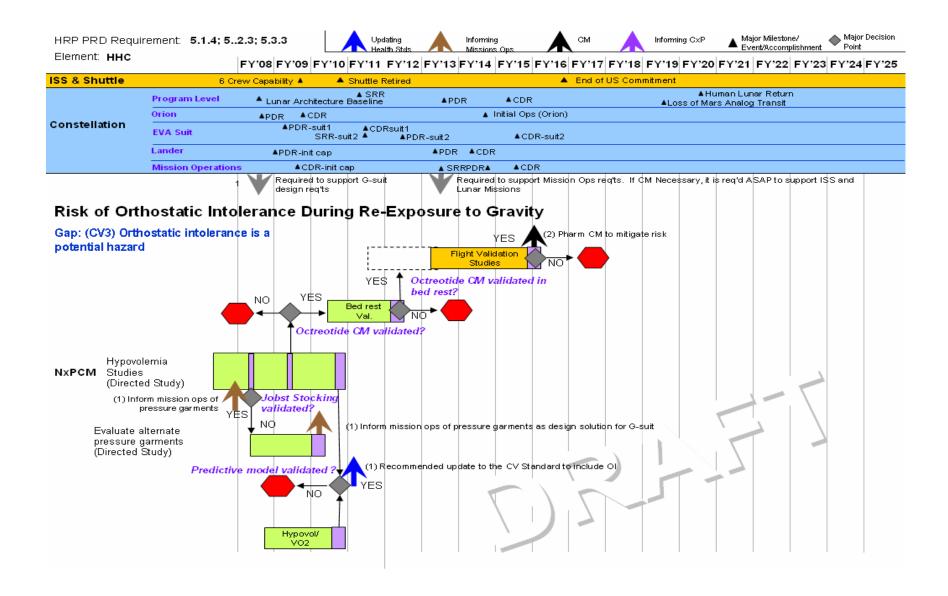
Project/Organization Responsible for Implementation of Activity:

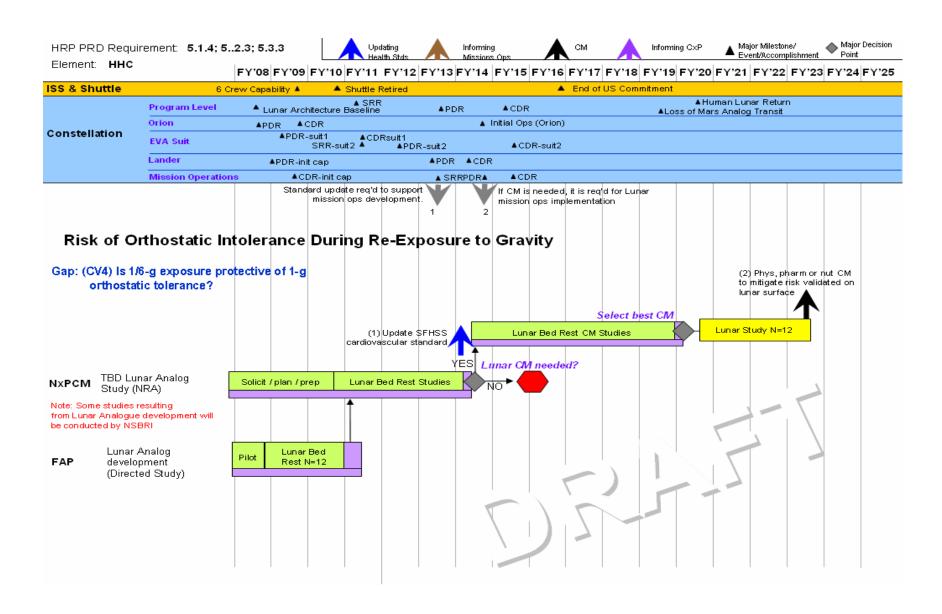
NxPCM – via NRA

Note that some studies resulting from the Lunar Analog study may be conducted by the NSBRI.



Graphics





16.0 RISK OF IMPAIRED PERFORMANCE DUE TO REDUCED MUSCLE MASS, STRENGTH AND ENDURANCE -D X I

There is a growing research database which suggests that skeletal muscles, particularly postural muscles of the lower limb, undergo atrophy and structural and metabolic alterations during space flight. However, the relationships between in-flight exercise, muscle changes and performance levels are not well understood. Efforts should be made to try to understand the current status of in-flight and post-flight exercise performance capability and what the goals/target areas for protection are with the current in-flight exercise program.

Operational Relevance and Risk Context

Successful lunar outpost and mars missions will require an adequate level of physical fitness. Mission tasks may range from simple intra-vehicular activities, to ambulation on a planetary surface, to construction of outpost habitats. The decrements that occur to skeletal muscle strength and endurance in response to reduced gravitational forces may make associated tasks more difficult to perform. Thus, impaired muscle performance may impact crew performance and mission success. It is important to identify Critical Mission Tasks, evaluate the muscle performance costs of these tasks (as related to provided tools and equipment), quantify the expected muscle performance decrements during lunar and mars missions, and design effective exercise countermeasures (hardware and prescriptions) that allow for mission success and safety with minimal time cost to additional mission operations. Will work closely with the engineering community to ensure that the EVA suit, tools and tasks will be designed to reduce the strength and endurance burden on the crewmember as much as possible.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

M1: What is the current state of knowledge regarding exercise performance?

Activity:

Knowledge compilation

The current state of knowledge of exercise in the development and maintenance of muscle mass, strength and endurance will be assessed. Published and unpublished data will be analyzed from ambulatory studies, bed rest studies and space flight.

Product/Deliverables:

State of Knowledge NASA technical manual

Information from this activity will guide Prescription Optimization Studies.

Findings will be used as input for the Digital Astronaut Program (DAP).

Required Delivery Milestone:

This work will occur during 2008.

Required Platforms:

Ground based analysis of existing data.

Project/Organization Responsible for Implementation of Activity:

Exercise Countermeasure Project (ECP) – via directed study

M7: Can the current in-flight performance be maintained with reduced exercise volume?

M8: What is the minimum exercise regimen needed to maintain fitness levels for tasks?

M9: What is the minimum set to equipment needed to maintain those (M8) fitness levels?

Activity:

Bed Rest Exercise Countermeasures Optimization

This study will develop minimal exercise countermeasures requirements will allow additional crewmember time to be dedicated to other tasks required for mission success. The minimal exercise volume, time and hardware required to maintain adequate muscle mass, strength and endurance will be determined. Optimized exercise countermeasures routines will be tested in subjects following prolonged bed rest with follow-up flight validation as needed.

Product/Deliverables:

Results from the Prescription Optimization Studies will determine if bed rest exercise countermeasure prescriptions have been optimized. The initial results will determine if follow-on flight validation studies to further optimize the prescription are required.

Required Delivery Milestone:

The initial milestone will be to inform mission operations in FY13 that the exercise prescription is optimized. If the data indicate the protocol cannot be optimized, then further flight studies will be initiated; countermeasure delivery to occur in FY20 and updates to the Health Standards to occur in FY20. All products are required by FY13 to support mission operations requirements development.

HRP-47065

Required Platforms:

The bed rest ground analog (6° head down tilt) is required for ground studies for countermeasure optimization. ISS will be required to validate any optimized countermeasures.

Project/Organization Responsible for Implementation of Activity:

ECP - via NRA or NSBRI solicitation

Activity:

ISS ARED Muscle Function Study

The Advanced Resistive Exercise Device (ARED) is gravity-independent exercise hardware that will be used for strength training aboard ISS. ARED will accommodate greater resistance loads than what is currently available to ISS crewmembers. ARED is instrumented to allow for measurement of muscle strength, power and endurance and will be used to monitor changes in muscle performance during flight. Results may determine if improved countermeasures and flight validation of countermeasures are needed.

Product/Deliverables:

Data that will guide decision of whether current countermeasures need only optimization (e.g., reduced volume, time) or if improved countermeasures and flight validation studies are needed.

Required Delivery Milestone:

The initial milestone will be to inform mission operations in FY13 that the exercise prescription is optimized. If the data indicate the protocol cannot be optimized, then further studies will be initiated with countermeasure delivery occurring in FY20 and updates to the Health Standards occurring in FY20. All products are required by FY13 to support mission operations requirements development.

Required Platforms:

ISS is required for instrumentation validation; if improved countermeasures are required the ground-based flight analog bed rest will be needed

Project/Organization Responsible for Implementation of Activity:

ECP – via directed study

Activity:

Center for Space Medicine (CSM) harness SDTO

Treadmill use in microgravity requires the use of a harness and a system to provide a subject load to keep the crewmember in contact with the treadmill belt. A common complaint from returning ISS crewmembers is that the current harness is uncomfortable. The pain and chafing that occurs with the use of the current harness contributes to sub-optimal subject loading (approximately 65% of body weight). A new

harness design will be tested to determine if it is more comfortable that the current harness and will allow for greater loading which is expected to result in better maintenance of muscle mass and bone density of the lower extremities

Product/Deliverables:

Decision to change to newer CSM harness or continue with current harness during treadmill activities

Required Delivery Milestone:

N/A

Required Platforms:

ISS

Project/Organization Responsible for Implementation of Activity:

Glenn Research Center ECL/ECP – via directed study

M10: What is the correct set of ground-based studies (bed rest and others) to optimize exercise prescriptions for Lunar Outpost and Mars?

Activity:

Lunar Analog Bed Rest Studies – TBD

A lunar bed rest model with simulated EVA tasks will be used to determine if lunar gravity combined with EVA activities are protective of muscle mass, strength and endurance or if additional resistance training will be required for mission success and safety.

Product/Deliverables:

Determination if lunar EVA is protective of muscle performance. Results will be used along with the Critical Mission Task Assessment (below) to determine if Lunar Bed Rest Countermeasures Studies are needed.

Required Delivery Milestone:

Potential lunar countermeasure information will be delivered to mission operations in FY20. This is required by FY13 to support mission operations requirements development. Potential lunar countermeasures will be validated on the lunar surface and the validated countermeasures will be delivered in FY23 to meet long-duration lunar mission requirements.

Required Platforms:

Lunar analog bed rest (9.5° head up tilt)

Project/Organization Responsible for Implementation of Activity:

ECP – via directed study

Activity:

An integrated musculoskeletal countermeasure battery for long-duration lunar missions

Product/Deliverables:

Required Delivery Milestone:

N/A

Required Platforms:

Lunar analog bed rest (9.5° head up tilt)

Project/Organization Responsible for Implementation of Activity:

NSBRI

M3: What tasks will be required for Lunar Sortie, Lunar Outpost and Mars missions?

M4: What are the physiologic costs of those (M3) tasks?

M6: Need to develop a standardized performance measure of readiness for the (M3) tasks.

Activity:

Critical Mission Task (CMT) Assessment

The human performance tasks that will be required in order to assure mission success and safety will be identified (e.g., post landing egress, suited 10 kilometer walk-back, and emergency crewmember rescue). The muscle performance requirements to perform these tasks will then be determined by biomechanical and metabolic analyses obtained during performance of these tasks.

Product/Deliverables:

Results from this study will drive requirements for exploration exercise hardware development.

Results from this study along with Lunar Bed Rest (above) will help to determine if Lunar EVA is protective for successful performance of critical mission tasks or if lunar mission analog bed rest studies are required prior to lunar validation studies.

Required Delivery Milestone:

Mission operations will be informed of hardware development in FY12; this information is required by FY13 to support mission operations requirements development.

Data will also be provided to develop potential lunar countermeasures that will be validated on the lunar surface and the validated countermeasures will be delivered in FY23 to meet long-duration lunar mission requirements.

Required Platforms:

Ground based studies utilizing the partial gravity simulator (POGO) and the Neutral Buoyancy Lab. Bed rest facilities including the lunar analog will be utilized if required. Validation of the tasks will require lunar surface operations.

Project/Organization Responsible for Implementation of Activity:

ECP – via directed study; collaborators include Constellation Program Ground and Mission Ops SIG and Constellation Program working groups (e.g., CEV Cockpit Working Group, etc.).

Activity:

Factors of Influence Studies (for CMT)

The effects of specific human factors such as gender, initial fitness level and hydration status on the ability to perform critical mission tasks will be assessed as supplemental studies to Critical Mission Task Assessment.

Product/Deliverables:

Data will feed CMT model.

Required Delivery Milestone:

Data will feed into critical mission task assessments FY09-FY12.

Data will also be provided to develop potential lunar countermeasures that will be validated on the lunar surface and the validated countermeasures will be delivered in FY23 to meet long-duration lunar mission requirements.

Required Platforms:

Ground based studies utilizing the partial gravity simulator (POGO) and the Neutral Buoyancy Lab. Bed rest facilities including the lunar analog will be utilized if required.

Project/Organization Responsible for Implementation of Activity:

ECP – via directed study

SM7: Need for an integrated post-flight functional task performance test to be used on returning ISS crewmembers. Develop and validate operational tests to define the linkage between functional capabilities and physiological changes. This task should include planetary EVA-like activities

Activity:

STS/ISS Functional Task Test

During space flight astronauts experience alterations in multiple physiological systems. These physiological changes include sensorimotor disturbances, cardiovascular deconditioning, and loss of muscle mass and strength. These changes lead to disruption in the ability to ambulate and perform functional tasks during the initial reintroduction

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to a gravitational environment and may cause significant impairments in performance of operational tasks immediately following landing on a planetary surface. To date changes in functional performance that result from physiological changes have not been systematically documented. Therefore, the goal of this study is to develop and evaluate an integrated set of functional and physiological tests and then use these tests to determine how postflight changes in sensorimotor, cardiovascular and muscle physiology impact postflight functional performance. These tests will be performed pre and postflight on astronauts exposed to short and long-duration space flight. The STS/ISS Functional Task Test will assess operational relevance of these changes by measuring the performance of specific exploration tasks (e.g., simulated seat egress, ladder climb, hatch opening, etc.). Additionally changes in functional performance will be mapped standard muscular, neurological, and cardiovascular measures. Data obtained from this study will facilitate the design of countermeasures that specifically target the physiological systems responsible for impaired functional performance.

Product/Deliverables:

Crew performance space normal data and physiological systems that require countermeasures in order to preserve performance of functional tasks will be identified.

Required Delivery Milestone:

Data obtained with this study will deliver information on performance of crew after spaceflight. The updates on crew performance will be continual with no definitive product delivered. If an established countermeasure is developed, it will be delivered in FY20.

Required Platforms:

STS (short term flights)

ISS (long term flights)

Project/Organization Responsible for Implementation of Activity:

ECP – via directed study

Activity:

Bed Rest Functional Task Test

A battery of functional tasks (see STS/ISS Functional Task Test above) will be assessed before and after bed rest (simulated micro/partial gravity). The ability of targeted countermeasures to maintain performance of functional tasks will be examined

Product/Deliverables:

Countermeasures that will preserve performance of functional tasks

Required Delivery Milestone:

Data obtained with this study will deliver information on performance of crew after bed rest. The updates on crew performance will be continual with no

definitive product delivered. If an established countermeasure is developed, it will be delivered in FY20.

Required Platforms:

The bed rest ground analog (6° head down tilt) is required for ground studies.

Project/Organization Responsible for Implementation of Activity:

ECP – via directed study

Activity:

Factors of Influence Studies (for Bed Rest Functional Task Test)

The effects of specific human factors such as gender, initial fitness level and hydration status on the ability to perform functional mission tasks will be assessed as supplemental studies to the Bed Rest Functional Task Test.

Product/Deliverables:

Results from factors of influence will determine if tailored countermeasures are need for specific groups or individuals.

Required Delivery Milestone:

N/A

Required Platforms:

The bed rest ground analog (6° head down tilt) is required for ground studies.

Project/Organization Responsible for Implementation of Activity:

ECP – via directed study

M3: What tasks will be required for lunar sortie, lunar outpost and Mars missions?

EPSP7: What surface ops concepts could maximize human performance of mission tasks as well as protect crew health?

Activity:

Evaluate Operations Concepts for Lunar Analogs

 $\begin{tabular}{ll} \underline{See} & Risk of Compromised Eva Performance and Crew Health due to Inadequate Eva Suit Systems - Gaps EPSP7 / M3 \\ \end{tabular}$

M4: Identify physiological cost of tasks required for lunar sortie, lunar outpost and Mars missions

EPSP3: What are the metabolic costs and ground reaction force (GRF) doses associated with EVA tasks in lunar sortie, lunar outpost and Mars missions?

Activity:

Determine Metabolic Costs and Ground Reaction Forces for EVA Tasks

<u>See</u> Risk of Compromised Eva Performance and Crew Health due to Inadequate Eva Suit Systems – Gaps EPSP3 / M4

M5: How will suit limit performance of lunar sortie, lunar outpost and Mars tasks?

EPSP1: What parameters of EVA suit design affect human performance and how can these designs be modified to increase efficiency in crew health and performance?

Activity:

Studies to Examine Factors that may Affect Human Performance While Working in an EVA Suit

<u>See</u> Risk of Compromised Eva Performance and Crew Health due to Inadequate Eva Suit Systems – Gaps EPSP1 / M5 / SM9

Activity:

Human Performance in Suit Prototypes, Qualification Units and Flight Suit Articles

<u>See</u> Risk of Compromised Eva Performance and Crew Health due to Inadequate Eva Suit Systems – Gaps EPSP1 / M5 / SM9

EPSP2: How much cardiovascular and resistive exercise and ground reaction force (GRF) dose does EVA provide in lunar sortie, lunar outpost and Mars mission?

Activity:

Calculate Cardiovascular and Resistive Exercises

Analyze physiologic data collected during Exploration Task studies and Lunar Concept of Operations Metabolic Profiles studies in multiple analog environments (EPSP1, EPSP3, EPSP4, and EPSP7). Calculate cardiovascular exercise, resistive exercise and ground reaction forces based on surface operations concepts.

Product/Deliverables:

Quantified cardiovascular exercise, resistive exercise and ground reaction forces due to extravehicular activity

Required Delivery Milestone:

TBD

Required Platforms:

Statistical analysis and modeling capability

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

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EPSP12: What will suited human performance be upon arrival at the lunar surface?

Activity:

Analyze Functional Task Test data

Collaborate with Investigators conducting the Functional Task Test to determine human performance degradation due to short-duration space flight. Analyze data collected in EPSP1 to determine human performance degradation due to the suit. Combine analyses and apply to the recommended operations concepts from EPSP7 to determine estimate for suited human performance upon arrival at the lunar surface.

Product/Deliverables:

Inputs to muscle fitness for duty standard

Required Delivery Milestone:

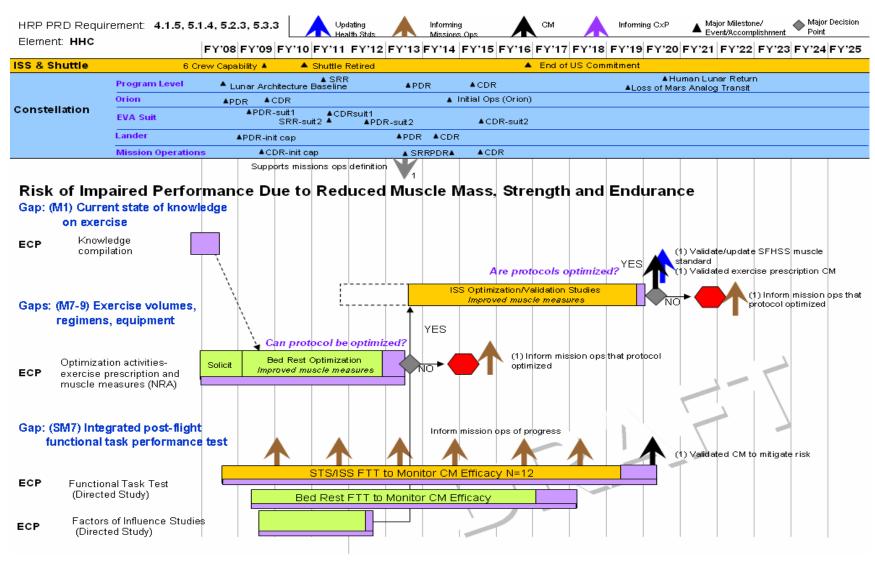
TBD

Required Platforms:

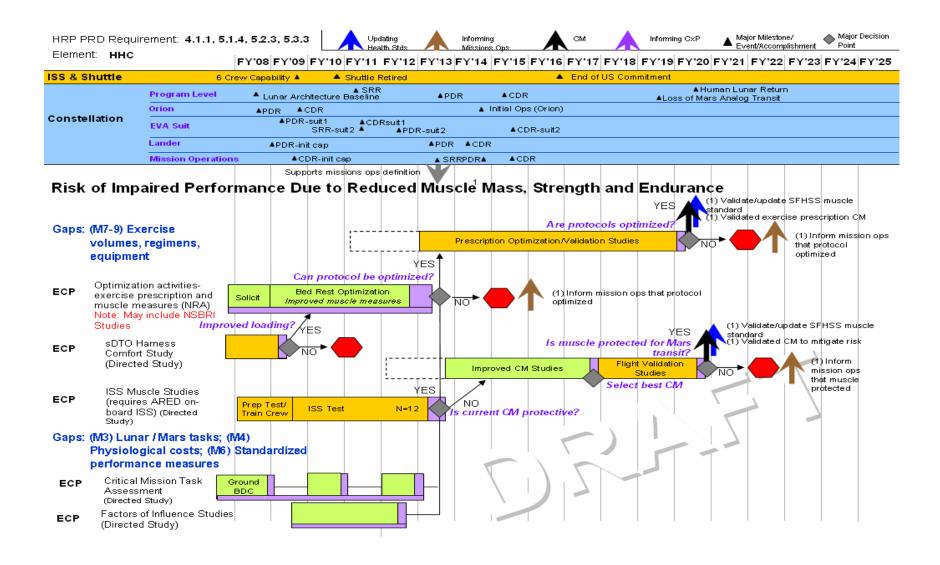
Lunar analog environment

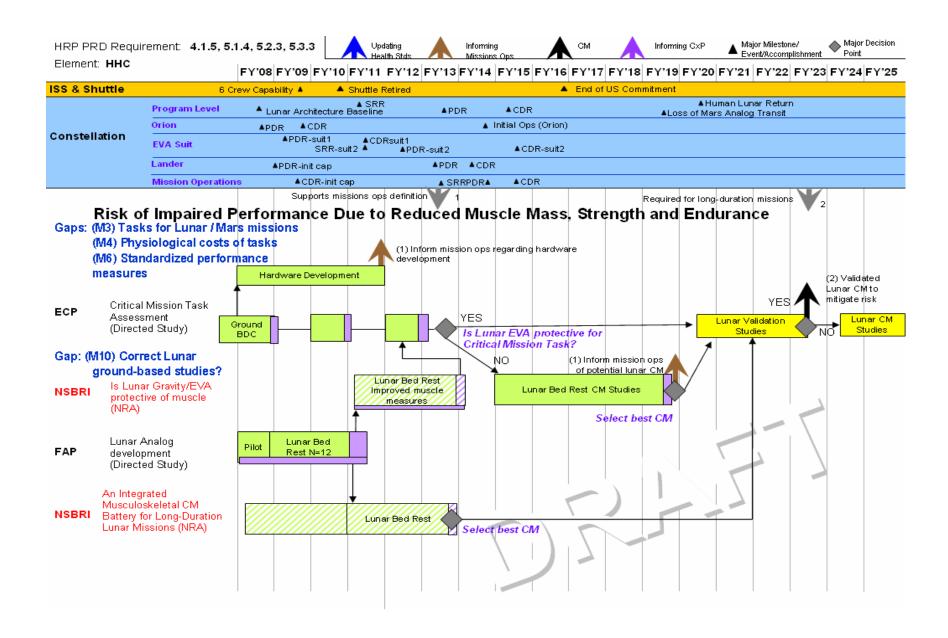
Project/Organization Responsible for Implementation of Activity:

EPSP - via directed study



Graphics





17.0 RISK OF REDUCED PHYSICAL PERFORMANCE CAPABILITIES DUE TO REDUCED AEROBIC CAPACITY -D X I

Astronauts' physical performance during a mission, including activity in microgravity and fractional gravity, is critical to mission success Setting minimum fitness standards and measuring whether crew can maintain these standards will document the effectiveness of maintenance regimens.

Operational Relevance and Risk Context

In addition to reduced skeletal muscle strength and endurance, reduced aerobic capacity may put mission success at risk. Evidence demonstrates that aerobic capacity is markedly reduced in response to space-flight and space-flight analogs. Sustained sub-maximal activities (walking on a planetary surface) could become difficult to perform if there are large enough decrements in aerobic capacity, though to date, astronauts have been able to perform strenuous mission activities. It will be important to identify Critical Mission Tasks and associated aerobic costs in order to design and validate effective exercise countermeasures for mission success. Current collaborative efforts with ESA are obtaining in-flight measurements of VO₂max aboard ISS. These measurements can be used as a baseline for future research to "optimize" or reduce the amount of in-flight exercise necessary to maintain performance.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

M1: What is the current state of knowledge regarding exercise performance?

Activity:

Knowledge Compilation

See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gap M1

M7: Can the current in-flight performance be maintained with reduced exercise volume?

M8: What is the minimum exercise regimen needed to maintain fitness levels for tasks?

M9: What is the minimum set to equipment needed to maintain those (M8) fitness levels?

Activity:

Prescription Optimization Studies

Developing minimal exercise countermeasures requirements will allow crewmember time to be dedicated to other mission tasks. The minimal exercise volume, time and hardware required to maintain aerobic capacity will be determined during bed rest with follow-up flight validation studies as required.

Product/Deliverables:

Results will be used for a go forward decision regarding implementing an ISS Exercise Optimization Validation study.

Required Delivery Milestone:

The initial milestone will be to inform mission operations in FY13 that the exercise prescription is optimized. If the data indicate the protocol cannot be optimized, then further studies will be initiated with countermeasure delivery occurring in FY20 and updates to the Health Standards occurring in FY20. All products are required by FY13 to support mission operations requirements development.

Required Platforms:

Ground based studies utilizing the partial gravity simulator (POGO) and the Neutral Buoyancy Lab. Bed rest facilities including the lunar analog will be utilized if required.

Project/Organization Responsible for Implementation of Activity:

ECP - via NRA or NSBRI solicitation

M10: What is the correct set of ground-based studies (bed rest and others) to optimize exercise prescriptions for Lunar Outpost and Mars?

Activity:

Lunar Analog Bed Rest Studies – TBD

See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gap M10

Activity:

<u>An Integrated Musculoskeletal Countermeasure Battery for Long-Duration Lunar Missions</u>

See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gap M10

CV2: Unknown in-flight and immediate post-flight VO_{2max}

M2: What is the current status of in-flight and post-flight exercise performance capability? What are the goals/targets for protection with the current in-flight exercise program?

Activity:

ISS/VO₂max Study

See Risk of Unnecessary Operational Limitations Due to Inaccurate Assessment if Cardiovascular Performance – Gap CV2

Activity:

Hypovolemia VO₂max Studies

Loss of plasma volume is hypothesized to be a major contributing factor to reduced aerobic capacity in response to space flight. An established ground-based model of microgravity-induced hypovolemia will be used to determine the effect of reduced plasma volume on VO_2 max.

Product/Deliverables:

Results from this study will aid Prescription Optimization Studies

Required Delivery Milestone:

Study will be conducted during the 2008-2010 timeframe and will feed data into the Bed Rest Prescription Optimization studies

Required Platforms:

Ground-based hypovolemia model

Project/Organization Responsible for Implementation of Activity:

NxPCM/ECP

M3: What tasks will be required for lunar sortie, lunar outpost and Mars missions?

M4: What are the physiologic costs of those (M3) tasks?

Activity:

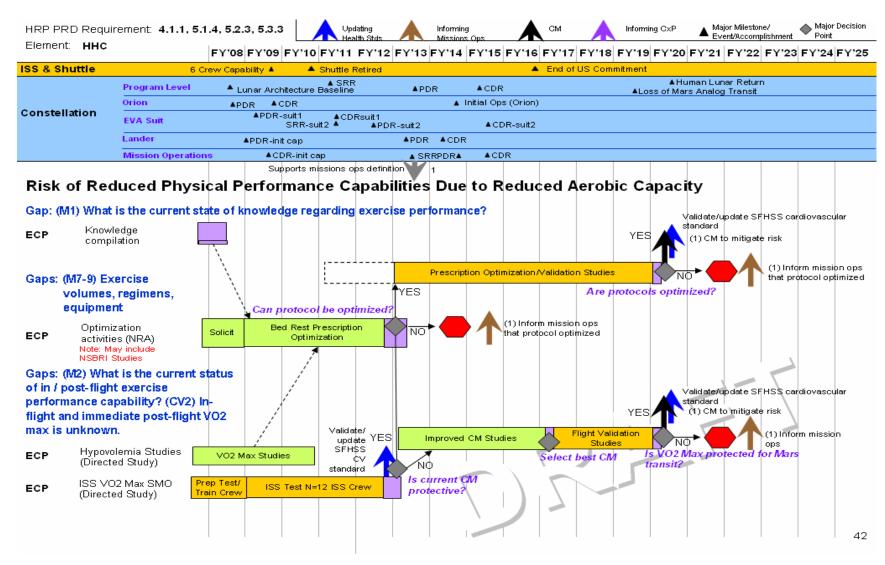
Critical Mission Task Assessment

See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gaps M3, 4, 6

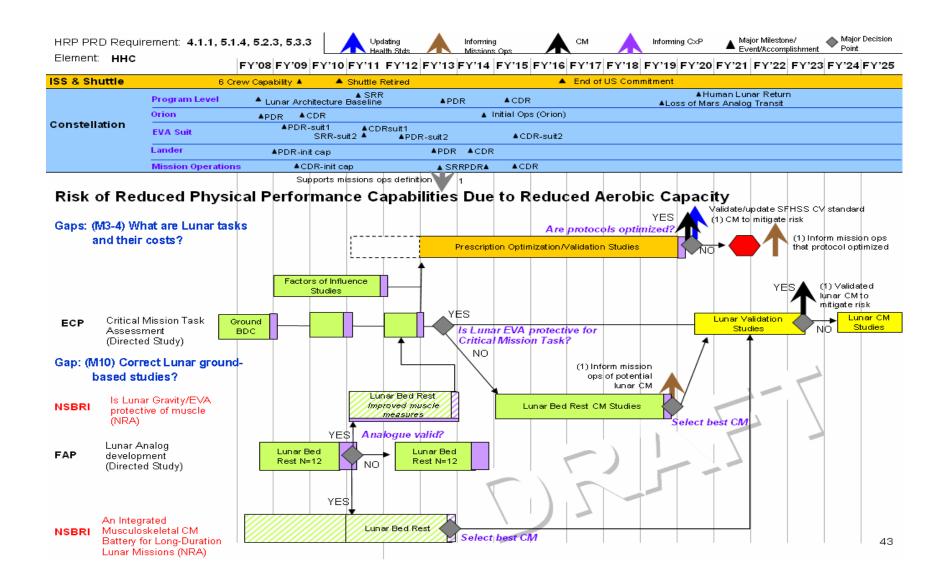
Activity:

Factors of Influence Studies (for CMT)

See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gaps M3, 4, 6



Graphics



18.0 RISK OF THERAPUTIC FAILURE DUE TO INEFFECTIVENESS OF MEDICATION -D X I

Based on subjective reports, drugs are effective during space flight. Better record keeping of medication use, efficacy and side effects will be instituted and those records will provide evidence for or against this risk. If medications are found to be ineffective, research will be performed to determine if drug metabolism is affected by space flight. Studies to determine if space flight affects drug stability are currently underway.

Operational Relevance and Risk Context

Better recordkeeping of medication use, efficacy and side effects should be instituted. It is particularly important to know what pharmaceuticals are taken prior to in-flight tasks. This will provide evidence for or and should be a precursor to a formal assessment of PK/PD on orbit. It is thought that the reduction in gastrointestinal (GI) motility and function, offered as the first piece of evidence for this gap, is not an issue after the first few days of flight. In general, oral medications are not prescribed during this period of the mission. It is not known to what extent different volumes of distribution might be a factor in flight. Drugs selected for the PK/PD studies should be commonly used, have few side effects, and different metabolic pathways. External consultants should be used to determine which drugs to test and to design testing protocols.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

PH6: Develop standard procedure for prospective analyses of drugs to be considered for flight and periodic analyses of drugs that are used for flight.

PH10: What are the performance effects of in-flight drugs on exercise, orthostatic tolerance, motor control, cognitive function, etc.?

CV6: Influence of in-flight medication use on physical and cognitive performance is not systematically documented.

Activity:

Terrestrial Drug Database Review – Data Mining TBD

Product/Deliverables:

Two items will be delivered: a final report of findings and a proposed standard procedure for prospective analyses of drugs to be considered for flight. Periodic analyses of drugs that are used for flight.

Required Delivery Milestone:

Data obtained by the completion of database review will inform procedure development and ultimately inform Flight Medicine by 2010.

Required Platforms:

Access to necessary pharmacological and Space Medicine databases is required.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

PH7: What are the effects of spaceflight on Pharmacokinetics/Pharmacodynamics?

Activity:

Bioavailability and Performance Effects of Promethazine (PMZ) During Spaceflight

Promethazine is currently given to treat motion sickness during space flight. The side effects associated with PMZ include dizziness, drowsiness, sedation, and impaired psychomotor performance. Anecdotal reports from crewmembers indicate that these central nervous system side effects of PMZ are absent or greatly attenuated in microgravity. Recent reviews of medical debriefs indicate that, at least in some crewmembers, there are significant central nervous system depressant effects. In addition, the pharmacokinetics and bioavailability of medications administered in microgravity may be different than on Earth which could significantly alter drug efficacy, as well as, the severity of side effects for a given dosage. This study will systematically evaluate PMZ bioavailability, effects on performance, side effects, and efficacy in the treatment of motion sickness to determine optimal dosage and best route of administration of PMZ in flight.

Product/Deliverables:

Complete study and report findings.

Required Delivery Milestone:

Study completion in 2009, final report of findings in 2010.

Required Platforms:

Space Shuttle is required for assessing spaceflight effects of PMZ.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

Activity:

Drug Efficacy Studies [data mining activity (proposal in-work)]

This study will review the available pharmacokinetic/pharmacodynamic and efficacy data from previous missions to develop and understanding of the bioavailability and uptake of pharmaceuticals in a microgravity environment. If results indicate drugs are ineffective, flight studies will be initiated to examine PK/PD.

Product/Deliverables:

Initial product is a final report of findings. If results indicate that drug effectiveness is diminished in flight, ISS pharmaceutical PK/PD studies will be solicited and performed. Follow-on studies to assess any necessary countermeasures will also be performed if necessary.

Required Delivery Milestone:

Ground-based data mining completion and report by 2009. Any required validated countermeasures will be delivered to mission operations in FY19. The potential countermeasures are required as soon as possible for current crew as well as for lunar mission operations requirements development.

Required Platforms:

Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study. ISS is required as the Mars transit analog for in-flight PK/PD studies and for countermeasure validation.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

PH9: What is the effect of long-term spaceflight on drug stability and what measures can be employed to extend the duration of drug efficacy?

Activity:

Stability of Pharmacotherapeutic and Nutritional Compounds: Stability SMO (Flight)

This protocol involves investigative physical/chemical analyses of both medications and food items returned from STS and ISS along with corresponding lot-matched controls stored on ground in a controlled environment. This experiment has 2 subpayloads attached to it. See the Risk of Inadequate Nutrition for the nutrition subpayload information. The Pharmacology Sub-Payload will identify pharmaceutical preparations at risk for degradation; characterize degradation profiles of the unstable formulations after exposure to ISS environment; and compare and contrast stability of ISS flown medications to their matching controls from the same lot and commercial packing conditions. This study will provide critical information about the susceptibility of medications and vitamins in the space food system to adverse environmental factors encountered during space missions.

Product/Deliverables:

Any new requirements or proposed new medications for flight will be submitted to mission operations. Data will be supplied to in-flight PK/PD studies.

Required Delivery Milestone:

Flight Medicine will be informed of any operational changes in FY09. This information is required by Flight Medicine as soon as possible.

Required Platforms:

ISS required for proper radiation doses on pharmaceutical samples.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

Activity:

<u>Assessment of Pharmaceutical Stability in Analog Environments of Space Missions:</u>
<u>Stability SMO (Ground)</u>

Previous reports suggest that the space flight environment may compromise chemical and physical stability of pharmaceuticals contained in the Space Shuttle and ISS medical kits. The Pharmacotherapeutics laboratory has demonstrated that exposure to gamma radiation on the ground can reduce the shelf life of certain pharmaceutical formulations. The objectives of this proposal are to systematically evaluate the following effects of spacecraft environmental factors using ground based analog environments: 1) cyclic temperature/humidity fluctuations, 2) vibrational stress, and 3) synchrotron light and radiation sources, on the chemical and physical stability of pharmaceutical formulations. This study uses radiation exposure to test the stability of various pharmaceutical components and will be compared to on-going flight data that is being collected.

Product/Deliverables:

The initial product is a series of radiation studies using ground-based radiation sources (Brookhaven, university or hospital facilities).

Required Delivery Milestone:

Data from the ground Stability study will feed into the flight Stability SMO.

Required Platforms:

Ground-based radiation sources (Brookhaven, university or hospital facilities) required for assessment of radiation doses on pharmaceuticals, and ground-based platforms may be required for follow-on studies.

Project/Organization Responsible for Implementation of Activity:

NxPCM - via directed study

PH1: Inadequate tracking of medication use, indication, efficacy and side effects.

PH3: What training methods and reference documents should be employed for training the crew and medical team to identify and mitigate side effects and interactions of commonly used medications?

Activity:

The HHC shall negotiate with SD to investigate methods to improve tracking of medication use, indication, efficacy and side effects during flight and to determine what training methods and reference documents should be employed for training the crew and medical team to identify and mitigate side effects and interactions of commonly used medications.

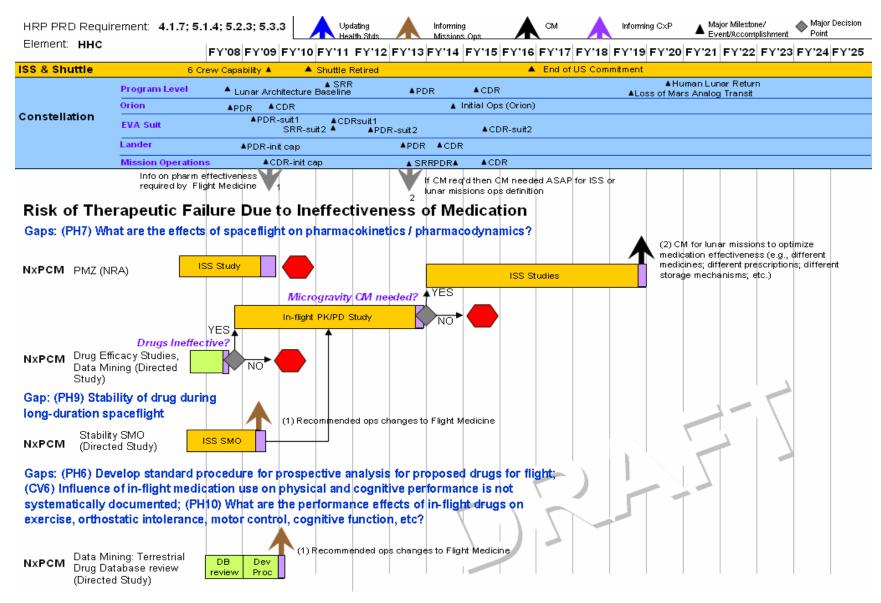
Product/Deliverables:

Required Delivery Milestone:

Required Platforms:

Project/Organization Responsible for Implementation of Activity:

SD



Graphics

19.0 RISK OF ERROR DUE TO INADEQUATE INFORMATION -D X I

Operator errors are common in all work environments. Task errors during human spaceflight missions could have drastic consequences. Errors can be due to lack of information which in turn may be due to any of the following: (a) lack of situational awareness, which can be due to poorly designed interfaces, poorly designed tasks, or cognitive decrements due to, e.g., fatigue or exposure to toxic environments; (b) forgetting, which can be due to inadequate training, poorly designed procedures, or to cognitive decrements due to, e.g., fatigue or exposure to toxic environment; (c) inability to access appropriate data and procedures due to poorly designed interfaces, poorly designed tasks, or to cognitive decrements due to, e.g., fatigue or exposure to toxic environments; or (d) failure of judgment due to incorrectly perceived or interpreted cues, inappropriately estimated results of decisions, or inadequate data. The risk is currently based on extensive data from commercial aviation, from nuclear power plant operations, and from other activities with high dependence on technology under sustained operations. The HRP must provide standards for reducing operator errors in spaceflight through adequate understanding of causes and mitigations of operator errors.

Operational Relevance and Risk Context

One of the most critical components for human presence in space has been ensuring that there are human systems standards in place that will provide for crew health as well as standards for habitability, environmental, and human factors. The Space Flight Human System Standards - SFHSS - (and the companion Human Integration Design Handbook – HIDH) require that each human spaceflight program derive program-specific, verifiable requirements to comply with the standards, and require that each human spaceflight program establish a human factors process involving health and human factors experts. This is to ensure that there will be identification of any standards in the SFHSS that are not applicable (or altered) and the rationale for non-applicability; that all program level health and human factors requirements are based on the HIDH, cited empirical evidence, or known best practices; and that end-items are in compliance with SFHSS, and agency and program level requirements and specifications.

The activities cited reflect the need to work toward the mitigation of identified SHFE risks by continuing to inform the standards, by engagement in the development of the requirements that will implement the standards based upon the resulting products, as well as providing content to the HIDH that will serve as the implementation guide. In addition, products resulting from these activities may provide valuable information to spaceflight programs that can inform the requests for trade studies.

To ensure operational relevance of the deliverables from the tasks, all tasks leaders will identify stakeholders who will work with them in framing the questions and approach. The stakeholders will participate by identifying specific issues requiring research or technology development, by reviewing progress, and by suggesting operational evaluations. Depending on the specific tasks, stakeholders may include engineers or operations personnel.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

SHFE1: New Display and control designs are required to meet the new environments of the Constellation system

Activity:

Display Development

This is a requirements development activity, supplemented by some research or validation activities on the ground. Produce requirements for display information density consistent with the smaller cockpit environments of the Orion CEV, the lander, and the Rover.

Product/Deliverables

Display and control design solutions for human computer interfaces for the Orion PDR and CDR.

Caution and warning and display requirements for the Lunar Lander SRR Caution and warning and display design solutions for the Lunar Lander Guidelines for EVA interfaces with suit, spacecraft, rover, and tool displays and controls.

Required Delivery Milestone

Orion PDR design solutions required FY-08

Orion CDR design solutions required FY09

Lander SRR Requirements required FY-12

Lander PDR design solutions required FY-13

Required Platforms

Laboratory Testbeds

Mockups

EVA Suit Development Facility, DESERT RATS

Project/Organization Responsible for Implementation of Activity

SHFE Directed Research Project.

Partnership with NSBRI teams for Human Performance Factors, Sleep and Chronobiology, Sensorimotor Adaptation, Smart Medical Systems, and Technology Development.

Activity:

Cursor Control

This is a technology survey and testing effort to determine the best solutions for crewmembers to make computer inputs under various vibratory environments and in gloved suits. These are intrinsic to commanding spacecraft and its subsystems.

Product/Deliverables

Cursor control design solutions for human computer interfaces for the Orion PDR and CDR.

Cursor control requirements for the Lunar Lander SRR Cursor control design solutions for the Lunar Lander

Required Delivery Milestone

Orion PDR design solutions required FY-08

Orion CDR design solutions required FY09

Lander SRR Requirements required FY-12

Lander PDR design solutions required FY-13

Required Platforms

Laboratory Testbeds

Mockups

EVA Suit Development Facility, DESERT RATS

Project/Organization Responsible for Implementation of Activity

SHFE Directed Research Project.

Activity:

Caution and Warning System Displays and Electronic Procedures

This is a technology survey and testing effort to evaluate advanced concepts for annunciation of events and display and paging of electronic procedures during a time critical event. It integrates procedural knowledge and knowledge bases with sensory data.

Product/Deliverables

Caution and Warning design solutions for the Orion PDR and CDR. Caution and Warning requirements for the Lunar Lander SRR Caution and Warning design solutions for the Lunar Lander

Required Delivery Milestone

Orion PDR design solutions required FY-08

Orion CDR design solutions required FY09

Lander SRR Requirements required FY-12

Lander PDR design solutions required FY-13

Required Platforms

Laboratory Testbeds

Mockups

EVA Suit Development Facility, DESERT RATS

Project/Organization Responsible for Implementation of Activity

SHFE Directed Research Project.

Partnership with NSBRI teams for Human Performance Factors, Sleep and Chronobiology, Sensorimotor Adaptation, Smart Medical Systems, and Technology Development.

Activity:

Information Presentation for EVA

This is a requirements development activity, supplemented by some research or validation activities on the ground. Produce requirements for presentation and navigation of displays of procedures, suit status sensors, navigation, and other information consistent with the unique environment of EVA suits.

Product/Deliverables

Guidelines for EVA interfaces with suit, spacecraft, rover, and tool displays and controls.

Required Delivery Milestone

Interfaces and approaches for Suit-1 PDR FY-09

Requirements for Suit-2 SRR FY-11

Interfaces and approaches for Suit-2 PDR FY-12

Required Platforms

Laboratory Testbeds

Mockups

EVA Suit Development Facility, DESERT RATS

Project/Organization Responsible for Implementation of Activity

SHFE Directed Research Project.

Partnership with NSBRI teams for Human Performance Factors, Sleep and Chronobiology, Sensorimotor Adaptation, Smart Medical Systems, and Technology Development.

SHFE2: Need for objective measures for proficiency in training; minimal time available for crew medical training.

Activity:

Medical Proficiency Training

Provide guidelines for the most efficient methods of training, and guidelines for the best media for presenting refresher training and just-in-time (JIT) training in flight. Development of a concept demonstration, in collaboration with Exploration Medicine team, using medical training as a test bed. This is not a research effort per-se. Rather; it is a review of training procedures and checklists to optimize to make emergency procedures and response more effective and timely.

Address method of delivery, duration, and timing of training for pre-flight and in-flight activities. Pre-flight training includes familiarization, core knowledge, and hands-on training in preparation for a space mission. In-flight training includes JIT training and refresher training.

Product/Deliverables:

Initial training materials integrated for ISS use:

- O Draft requirements for optimal training type, duration and timing (with respect to anticipated task performance).
- Sample training module for use in ground personnel training.
 Complete Training Materials and Medical Procedures Library for use in lunar exploration missions

Required Delivery Milestone:

FY10 Initial training materials and medical procedures integrated (Required as soon as practically available for ISS)

FY14 Training materials integrated into Lunar operations and medical procedures library available for Lunar surface PDR

Required Platforms:

Ground Studies

Project/Organization Responsible for Implementation of Activity:

SHFE Directed Research Project.

Partnership with NSBRI teams for Human Performance Factors, Sleep and Chronobiology, Sensorimotor Adaptation, Smart Medical Systems, and Technology Development.

Activity:

Spaceflight Resource Management Training

Work with MOD to incorporate training on roles responsibilities and communications during intensive flight activities, similar to cockpit resource management concepts that

are employed in the aviation industry. These materials are not specific training materials themselves, but are designed to incorporate the concepts of cockpit resource management into all MOD training materials. This is not research per-se, but rather an organizational effort to update the training materials and requires coordination with MOD training.

Product/Deliverables:

New modules of training materials incorporating Spaceflight Resource Management concepts (3 examples)

Complete training library with Spaceflight Resource Management concepts incorporated.

Required Delivery Milestone:

FY14 Training materials integrated into Lunar operations training library available for Lunar surface PDR

Required Platforms:

Ground Studies

Project/Organization Responsible for Implementation of Activity:

SHFE Directed Research Project.

SHFE3: Need for on-board crew to semi-autonomously plan and dynamically replan their schedules and activities. Scheduling, rescheduling and real-time changes are done manually and are labor intensive.

Activity:

Science Planning Interface to Engineering (SPIFe) – Scheduling Tool

Future mission concepts will require a significantly more efficient planning process and tools. The ultimate goal of this effort is to allow an on-board crew to semi-autonomously plan and dynamically replan their activity. Based on a firm understanding of ground-based replanning in several domains, the activity will be well-positioned to understand and develop tools for on-board use. The SPIFe tool considers a wide range of the dynamic resources constraining schedule and allows the crewmember to schedule tasks and check that the resources required to execute the task will be available, and that there are no unintended consequences of scheduling the task at a particular time (such as not being able to execute another required task at a later time). Development of this tool is almost complete, and then a decision will be made regarding its utility for spacecraft operations planning and if required, the tool will be validated in an operationally-intensive ground analog (e.g. NEEMO). A functional prototype could be run alongside existing tools to collect valuable data on the tool and its capability to optimize a schedule.

Product/Deliverables:

Planning tool, validated in a ground analog available for use on the ISS Planning tool, validated in a ground analog available for use for Lunar Outpost Operations

Required Delivery Milestone:

FY-12 SPIFe, could be integrated into crew operations as soon as available in ground-validated form

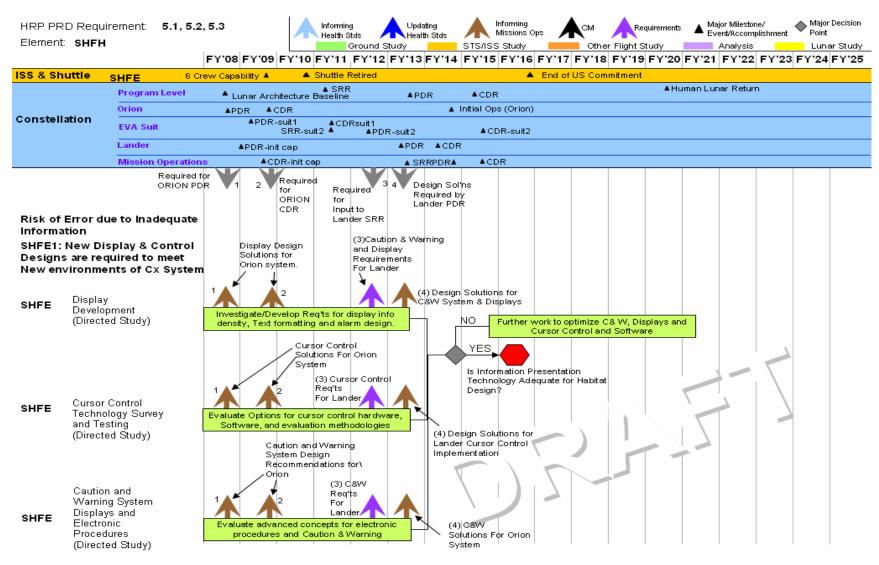
~FY22 SPIFe needed to support Lunar Outpost long-duration operations (Note: SPIFe is not envisioned to support lunar sorties because of the short duration and schedule-intensive advanced planning that must occur for these missions.)

Required Platforms:

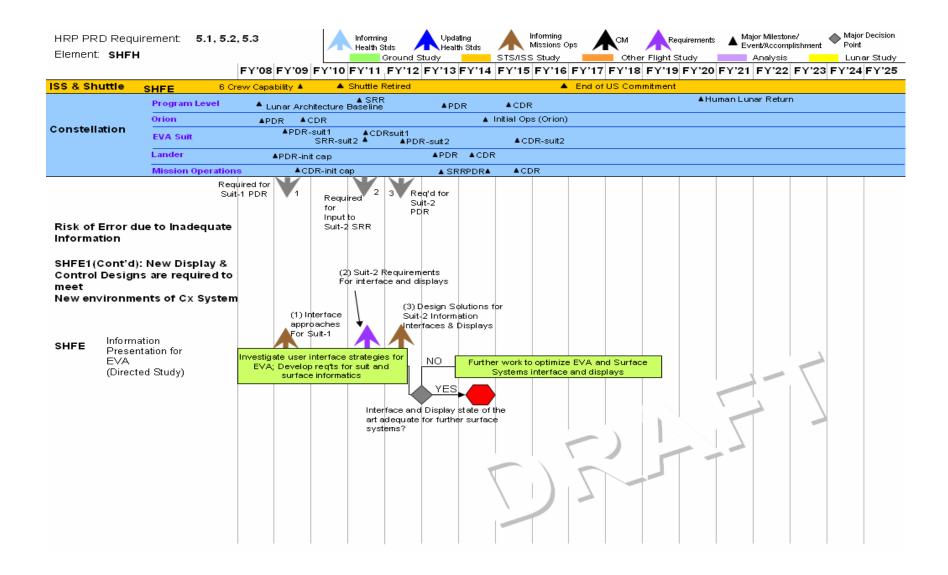
Ground or analog studies

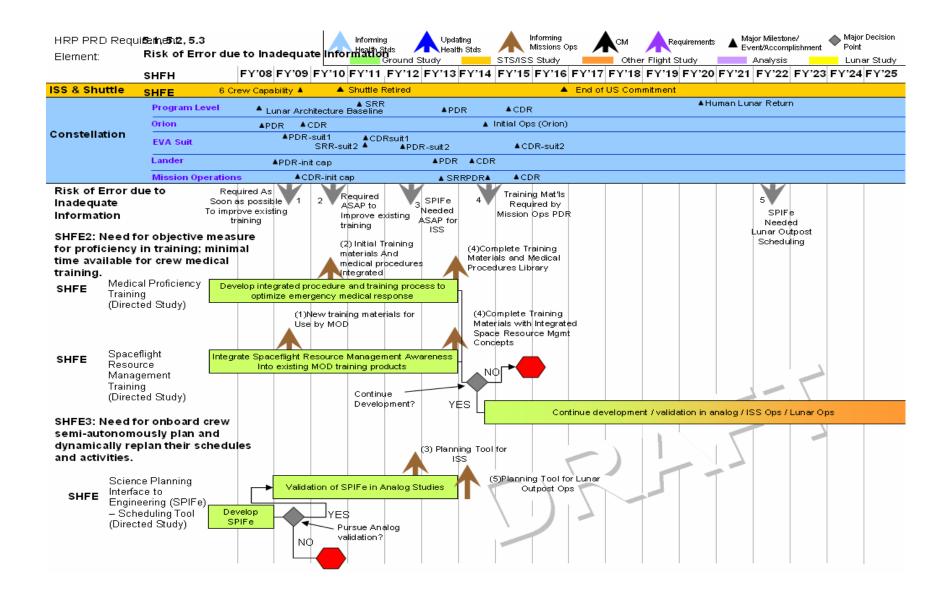
Project/Organization Responsible for Implementation of Activity:

SHFE Directed Research Project



Graphics





20.0 RISK ASSOCIATED WITH POOR TASK DESIGN -D X I

Errors are often related to poor task design. Critical tasks must be designed to minimize operator error. Automation, feedback and other task design elements may be used in these cases. Multiple actors, including robots, present a unique risk.

Operational Relevance and Risk Context

One of the most critical components for human presence in space has been ensuring that there are human systems standards in place that will provide for crew health as well as standards for habitability, environmental, and human factors. The Space Flight Human System Standards - SFHSS - (and the companion Human Integration Design Handbook – HIDH) require that each human spaceflight program derive program-specific, verifiable requirements to comply with the standards, and require that each human spaceflight program establish a human factors process involving health and human factors experts. This is to ensure that there will be identification of any standards in the SFHSS that are not applicable (or altered) and the rationale for non-applicability; that all program level health and human factors requirements are based on the HIDH, cited empirical evidence, or known best practices; and that end-items are in compliance with SFHSS, and agency and program level requirements and specifications.

The activities cited reflect the need to work toward the mitigation of identified SHFE risks by continuing to inform the standards, by engagement in the development of the requirements that will implement the standards based upon the resulting products, as well as providing content to the HIDH that will serve as the implementation guide. In addition, products resulting from these activities may provide valuable information to spaceflight programs that can inform the requests for trade studies.

To ensure operational relevance of the deliverables from the tasks, all tasks leaders will identify stakeholders who will work with them in framing the questions and approach. The stakeholders will participate by identifying specific issues requiring research or technology development, by reviewing progress, and by suggesting operational evaluations. Depending on the specific tasks, stakeholders may include engineers or operations personnel.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

SHFE4: Guidelines are needed for appropriate task automation as well as for effective allocation of tasks between humans and automation to increase performance, efficiency, and safety.

Activity:

Automation Interface Design Tools Development

The task will focus on the development of methods and tools to help with the challenge of optimally distributing functions between automation and human operators in space and on the ground, during both the mission architecture definition and hardware/software design processes, based on analyses of integrated human-system performance.

Tools to assist designers when they are designing automated modes, the various modes of operation and communicating those various modes and to ensure that all modes are identified and properly reviewed and addressed by the designer.

Product/Deliverables

Automation Evaluation Methods and Tools

Required Delivery Milestone

Insert into ISS Mission Ops (Attitude Controllers) FY08

Demonstrate Task Decomposition Tool, Performance Modeling Tool and Interface Prototyping Tool to support EVA Suit 2 SRR, FY11.

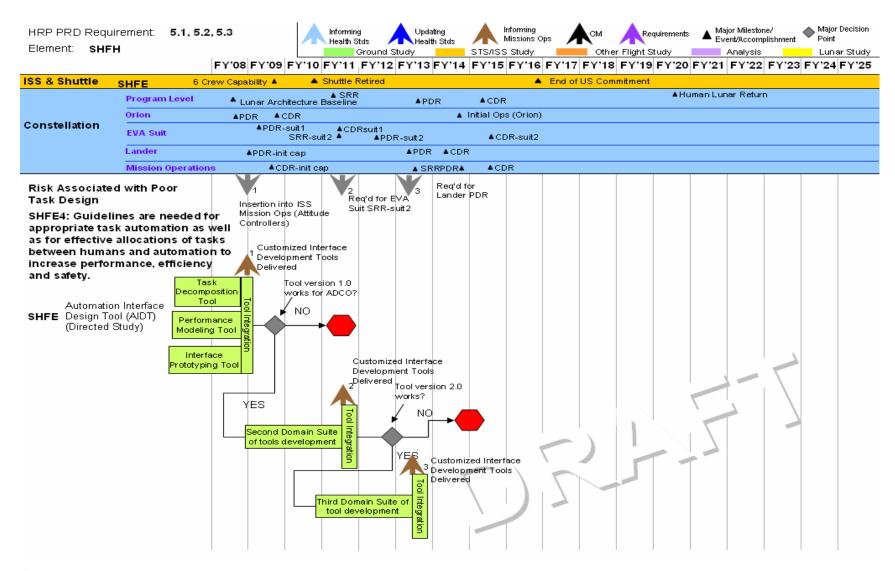
Demonstrate Task Decomposition Tool, Performance Modeling Tool and Interface Prototyping Tool, Required for Lander PDR FY13.

Required Platforms

Ground or analog studies

Project/Organization Responsible for Implementation of Activity

SHFE Directed Research Project



Graphics

21.0 RISK OF REDUCED SAFETY AND EFFICIENCY DUE TO POOR HUMAN FACTORS DESIGN -D X I

Inadequate human factors design in the physical work environments (e.g. vehicles, tools and tasks) will result in reduced human performance and increase the likelihood of errors. Research is needed to provide spaceflight human factors design data and design tools in microgravity and partial gravity.

Operational Relevance and Risk Context

One of the most critical components for human presence in space has been ensuring that there are human systems standards in place that will provide for crew health as well as standards for habitability, environmental, and human factors. The Space Flight Human System Standards - SFHSS - (and the companion Human Integration Design Handbook – HIDH) require that each human spaceflight program derive program-specific, verifiable requirements to comply with the standards, and require that each human spaceflight program establish a human factors process involving health and human factors experts. This is to ensure that there will be identification of any standards in the SFHSS that are not applicable (or altered) and the rationale for non-applicability; that all program level health and human factors requirements are based on the HIDH, cited empirical evidence, or known best practices; and that end-items are in compliance with SFHSS, and agency and program level requirements and specifications.

The activities cited reflect the need to work toward the mitigation of identified SHFE risks by continuing to inform the standards, by engagement in the development of the requirements that will implement the standards based upon the resulting products, as well as providing content to the HIDH that will serve as the implementation guide. In addition, products resulting from these activities may provide valuable information to spaceflight programs that can inform the requests for trade studies.

To ensure operational relevance of the deliverables from the tasks, all tasks leaders will identify stakeholders who will work with them in framing the questions and approach. The stakeholders will participate by identifying specific issues requiring research or technology development, by reviewing progress, and by suggesting operational evaluations. Depending on the specific tasks, stakeholders may include engineers or operations personnel.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

SHFE5: ISS Noise levels exceed levels specified in requirements; tools and models are not currently available for Constellation vehicle design verification.

Activity:

<u>Develop and Validate Models That Can be Used for Verification in CDR Design of Constellation Vehicle Systems</u>

This activity will enhance the capability of existing models and modify them for application to the Constellation designs. These models will be assessed for adequate parameter complexity and accuracy.

Product/Deliverables

Verification model for Constellation Orion vehicle

Required Delivery Milestone

FY08 for Orion PDR

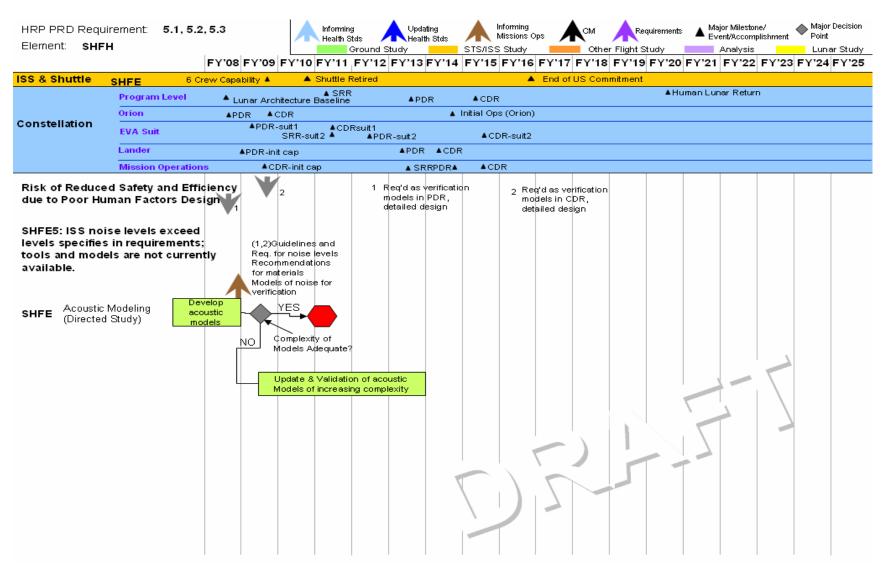
FY09 for Orion CDR

Required Platforms

Ground development

Project/Organization Responsible for Implementation of Activity

SHFE Directed Research Project



Graphics

22.0 RISK OF PERFORMANCE ERRORS DUE TO POOR TEAM COHESION AND PERFORMANCE, INADEQUATE SELECTION/TEAM COMPOSITION, INADEQUATE TRAINING, AND POOR PSYCHOSOCIAL ADAPTATION -D X I

Human performance errors may occur due to problems associated with working in the space environment and incidents of failure of crews to cooperate and work effectively with each other or with flight controllers have been observed. Interpersonal conflict, misunderstanding and impaired communication will impact performance and mission success. The history of spaceflight crews regarding team cohesion, training and performance has not been systematically documented. Tools, training and support methods should be provided to reduce the likelihood of this risk and improve crew performance.

Operational Relevance and Risk Context

While little empirical data have been collected regarding the impact of interpersonal and intrapersonal factors on spaceflight performance, it is possible that crew conflict could jeopardize a long duration Exploration Missions. Reports from MIR reveal that several missions may have been terminated earlier than planned due to interpersonal frictions between crewmembers, and some veteran NASA astronauts have reported crew conflict during previous space travels. Understanding the potential negative impacts of interpersonal and intrapersonal issues on spaceflight and analog environments is critical for identifying actions required to help crewmembers succeed during new types of missions (e.g., Mars Missions). Few individuals have spent one year or longer in isolated and confined environments, and a Mars Mission could be as long as three to five years in duration. Observations and "lessons learned" from previous space missions and from analog environments are critical sources of information required to inform these efforts. In preparation for Exploration Missions, BHP research focuses on preventing and mitigating the risk of performance errors due to inadequate Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation. Monitoring tools, countermeasures, training requirements, and selection recommendations are needed to aid flight crews and ground support teams.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

BHP 2.1.4 What is the experience of spaceflight crews regarding team cohesion, psychosocial adaptation, and training? (Priority 1) $\,$

The behavioral health experience of crews has not been systematically documented. This approach will inform the development of strategies for improving crew cohesion and communication, as well as adapting tools or measures to help monitor, detect, and prevent potential problems.

Activity:

Systematic Procedure: Crew History Report

Review of existing crew information and literature from analogs to examine small groups in extreme environments; debrief questionnaire development and analysis of current and future long-duration crews regarding their experiences, emphasizing interpersonal factors. This is largely a clinical activity until data from a sufficient number of subjects are collected.

Product/Deliverables:

- 1) Crew History Report provides recommendations based on existing spaceflight and analog experience of crews, including training, in-flight, and post-flight events.
- 2) Systematic procedure for collecting behavioral health data regarding interpersonal relations and crew dynamics from returning long duration astronauts.
- 3) Updates to Standards, if applicable.

Required Delivery Milestone:

Crew History Report based on current anecdotal evidence and analog evidence delivered in 2008. Systematic procedure delivered to Med Ops in 2008. Updates to recommendations made once thirty subjects have been evaluated, with subsequent updates following every four years. Recommendations required by 2013 for Mission Ops Requirements Definition and 2023 for Lunar Habitat Mission Ops. Standards update in 2012.

Required Platforms:

Ground based research.

Project/Organization Responsible for Implementation of Activity:

Directed Study, in collaboration with CB and SD

BHP Gap 2.2.1 What are the most effective methods for maintaining crew cohesion and ground communication, to manage and resolve conflict in space? (Priority 1)

Given the extended duration and confinement of Exploration Missions, strategies to promote crew cohesion and effective communication will be needed. Development of strategies and countermeasures, including development of training protocols, and new monitoring methods and tools may address this gap.

Activity:

Optimal Communication and Conflict Management

Lab studies that examine the impact of environmental stressors, incentives, and crew configuration changes on communication and performance within simulated space crews and between simulated space and ground crews.

Obtain and analyze data on crew cohesion and optimal communication methods during spaceflight, including communications between space and ground crews, in order to develop recommendations for improved communication strategies related to performance of mission objectives.

Ground tests to validate and optimize existing conflict management technologies to support crew cohesion and ground communication.

If flight data collected reveals that additional countermeasures are needed to address cohesion and communication, additional studies will be developed to help design and test new strategies.

Product/Deliverables:

- 1) Recommendations for optimal communication strategies
- 2) Technologies that provide conflict management support and guidance for crewmembers, particularly for autonomous operations.
- 3) Updates to Standards, if applicable.

Required Delivery Milestone:

In-flight validation to begin in 2012, and Mission Ops to be informed by 2013 with Recommendations in preparation for Lunar Mission Design. Conflict Management Technology to be delivered by 2014. Updates to Recommendations made in 2015, upon completion of flight validation. Standards update in 2012.

Recommendations due by 2013, and technologies due by 2014.

Required Platforms:

Flight data for past and future flights can be collected pre and post flight. Conflict management technology to be evaluated in analogs, including NEEMO, Haughton-Mars and the Antarctic. Flight validation of technology and Recommendations to occur on ISS.

Project/Organization Responsible for Implementation of Activity:

TBD

Gap 2.3.1 What are the best methods for training crews for maintaining cohesion and optimal performance during exploration missions (TBR-11)? (Priority 1)

Crews on ISS are multicultural, and this diversity will most likely continue for Exploration Missions. Finding adequate time for crews to train together continues to remain a challenge. These factors make it essential to determine what acceptable alternatives to traditional team training methods (i.e. virtual team training) exist. In addition, the type of team training activities (role playing, etc.) and the duration of the training are important factors in designing the most efficient and effective training model. It is critical to capture what type, dose, style and length of training can most adequately cover multiple competencies to ensure efficiency of the astronauts' time while ensuring mastery of the required competencies.

Activity:

Training Studies

Lab simulations to evaluate relationships between types of training, and their effects on cohesion and performance. These lab simulations allow for control of the type of training each team goes through, so that an accurate assessment of team training style on cohesion and performance can be determined.

Analog studies to validate optimal training methods; further validation to occur during NASA training with astronauts and flight controllers. Evaluate Training Requirements during spaceflight to determine if Training Requirements are adequate.

If further Training Requirements are needed, ground based studies will commence and will be followed by a phase of in-flight validation and lunar studies.

Product/Deliverables:

1) Requirements, crew training for team cohesion and optimal performance.

2) Update to Standards, if applicable.

Required Delivery Milestone:

Delivered by 2012 for Mission Operations; Update Standards in 2012. Required by 2013 for Mission Operations

Required Platforms

This effort, at this time, is primarily lab studies, analogs (NEEMO, HMP, Antarctic), and data mining; validation to require ISS.

Project/Organization Responsible for Implementation of Activity:

ITA with ARC

BHP 2.1.1 What methods and technologies can be developed to monitor individual and crew coping with the behavioral conditions of spaceflight? (Priority 2)

During Exploration Missions, and especially during a Mars Mission, real time communication between the crew and flight surgeons will not be available as it is now on ISS. Flight surgeons have stated the need for unobtrusive monitoring tools that are transparent to crews, require minimal crew time or effort, and that help detect if crews are having difficulties coping with the spaceflight environment.

The aim of the current Requirements is to develop a tool that detects changes in crew cohesion that may be precursors of crew dysfunction and poor performance. Such a tool would evaluate, as a measure of crew cohesion, changes in communication patterns (e.g., ratio of positive affect to total communication for given period). The tool would enable in real-time, an objective evaluation of crew dynamics and scheduling of risk mitigation countermeasures, as needed.

Monitoring tools identified in the Risk of Behavioral and Psychiatric Conditions may also provide an assessment of team cohesion. These tools (e.g., voice acoustics and facial expression recognition) will be validated in ground studies through 2010, and validated in flight through 2012 (more information can be found in Gap 3.1.1).

Activity:

Develop Requirements for Crew Communications Technology

Activities include evaluating various existing techniques for assessing team cohesion through crew communication, validating these techniques in analog environments and during astronaut training, and validating on ISS.

Preferred techniques will be developed into Requirements for an automated, unobtrusive tool to be utilized during Exploration Missions.

If after undergoing flight validation, these techniques are found to be not effective, additional research to occur on ground and on ISS. New Requirements will then be delivered by 2023 for informing Mission Ops and Input to Mars Ops Development.

Product/Deliverables:

- 1) Requirements for Crew Communications Technology (unobtrusive, passive measures that assesses changes in crew communication patterns as a measure of modified cohesion).
- 2) Updates to Standards (if applicable).

Required Delivery Milestone:

Delivered for Mission Operations by 2013. Standards updates by 2012.

Techniques are required to inform Mission Ops by 2013.

Required Platforms:

Ground studies to adapt technology for spaceflight; analogs include NEEMO, Haughton Mars Project (HMP), and other Isolated, Confined and Extreme (ICE) Environments. Validate on ISS, as the ISS will emulate the transit environment to Mars.

Project/Organization Responsible for Implementation of Activity:

NASA ITA with Ames

BHP 2.1.3 Does increased autonomy impact crew cohesion and performance? (Priority 2)

As crews begin operations for long duration missions beyond low Earth orbit, they will need to exercise increasing command and control of their daily activities. The distance for Mars Missions will result in loss of capability for real-time communication, downlink, and commanding. Likewise, the crew will have to augment and adapt their schedules based on real time changes in their schedules. Medical Operations has requested a study of crew autonomy while we are still in low Earth orbit, to identify (if any) the impact of increased autonomy on crew dynamics and performance.

Activity:

Autonomy Studies

Studies in analog environments (including NEEMO) evaluating the impact of increased autonomy on crew dynamics and performance. Workshop to examine preliminary results from analog studies and further define role of autonomy in Mars exploration and its effects on crew performance and crew dynamics. Studies on ISS to observe crew performance and cohesion, working under a low autonomy condition versus a high autonomy condition.

If evidence exists that increased autonomy impacts crew dynamics and performance, the need for countermeasures in addition to what BHP has developed/is developing, will be considered.

Product/Deliverables:

- 1) Recommendations based on the impact (if any) of increased autonomy in analogs and spaceflight.
- 2) Input for ISS as needed.
- 3) Updates to Standards, if applicable.

Required Delivery Milestone:

ISS data collection to be completed by 2015; Mission Ops for Lunar Habitat missions to be informed in 2015

Recommendations to Mission Ops for Lunar Habitat missions are due by 2023.

Required Platforms:

Requires analogs (NEEMO) and ISS

Project/Organization Responsible for Implementation of Activity:

NRA

BHP Gap 2.2.2 What are the most effective countermeasures for mitigating stress and deteriorated morale in order to optimize performance? (Priority 2)

Activity:

TBD

Product/Deliverables:

TBD

Required Delivery Milestone:

TBD

Required Platforms:

TBD

Project/Organization Responsible for Implementation of Activity:

TBD

Gap 2.3.2 What are the best methods and tools for selecting and composing crews for optimal team performance during Exploration Missions (TBR-12)? (Priority 3)

Group cohesion plays an important role in team performance: cohesive teams perform higher than less cohesive teams. Research demonstrates team selection factors influence team cohesion; thus, it is important to examine and implement practices to secure the best crew composition for Exploration Missions. Therefore, BHP's third priority within the Team Risk addresses recommendations for astronaut selection and team composition for Exploration Missions.

Activity:

Crew Composition Studies

Lab simulations allow for teams to be tasked with strenuous endeavors that simulate planetary surface activities (i.e. searching for moon rocks, water), with manipulation of variables within a controlled environment to examine cause and effect. Thus, the impact of personality factors and other various individual on differences on performance and cohesion can be observed. Lab simulations provide an efficient and cost effective way to build a knowledge base prior to going to an analog environment and then to spaceflight.

Following lab simulations, a review research from analogs to determine optimal selection criteria for crew cohesion and performance will be conducted. Assess factors of ISS crew and how those are related to measures of cohesion and performance. Develop composition and selection recommendations for Exploration Missions.

Product/Deliverables:

1) Recommendations, composition and selection.

2) Update Standards.

Required Delivery Milestone:

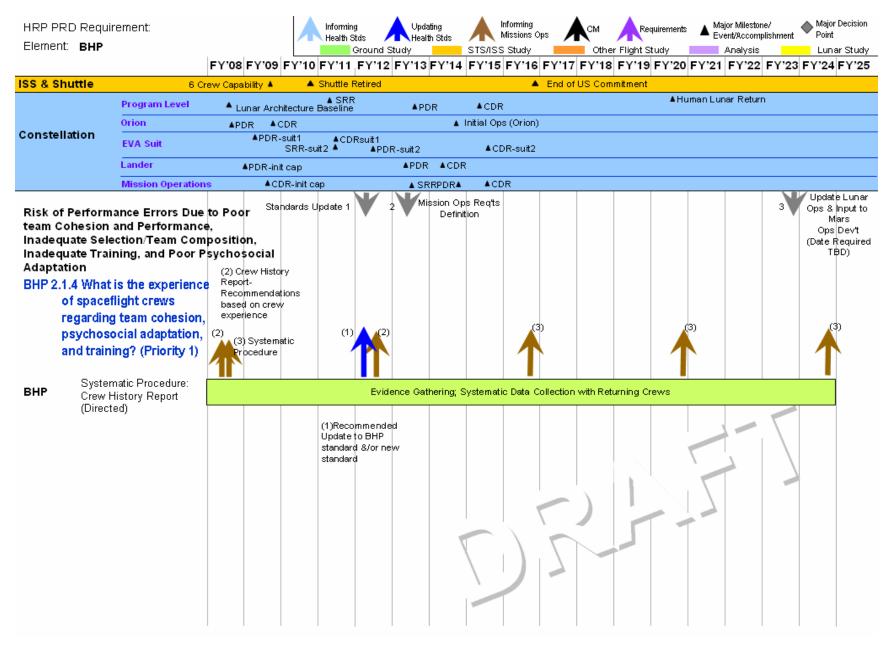
Inform Mission Ops for Lunar Habitat missions in 2015. Recommendations required by 2023.

Required Platforms:

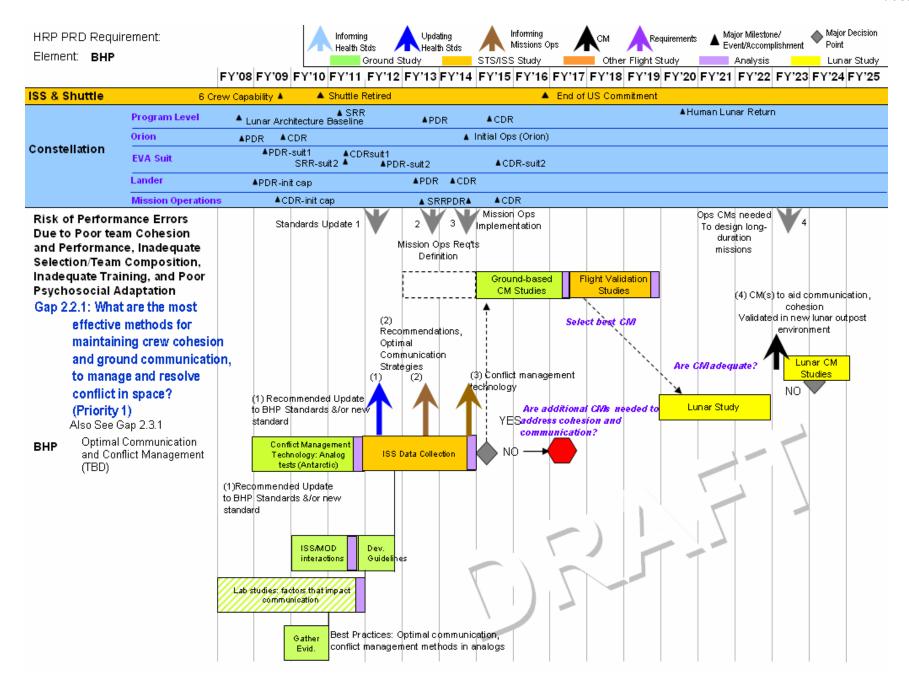
This effort is primarily ground studies and data mining effort.

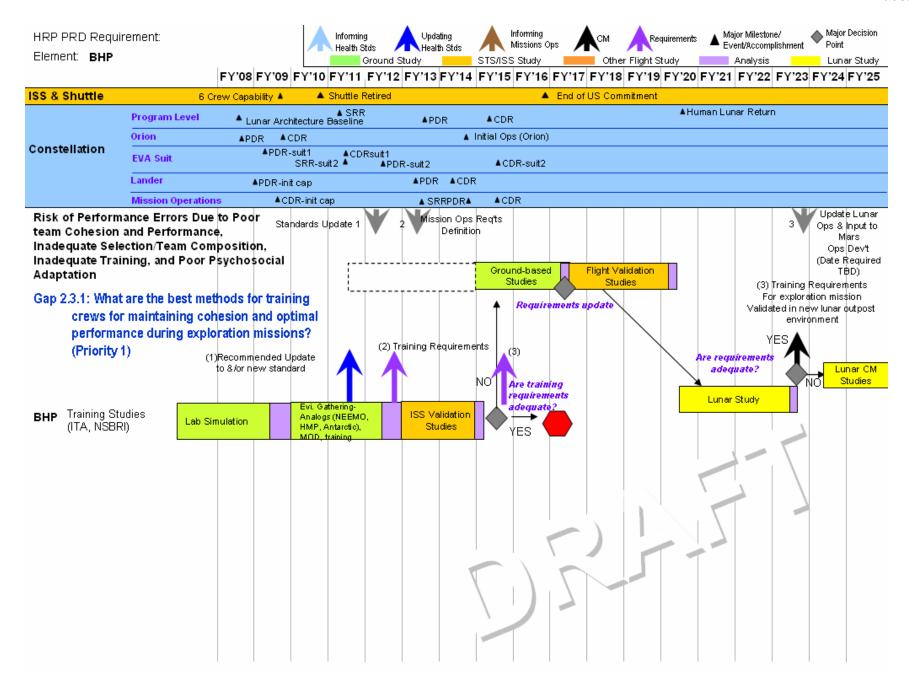
Project/Organization Responsible for Implementation of Activity:

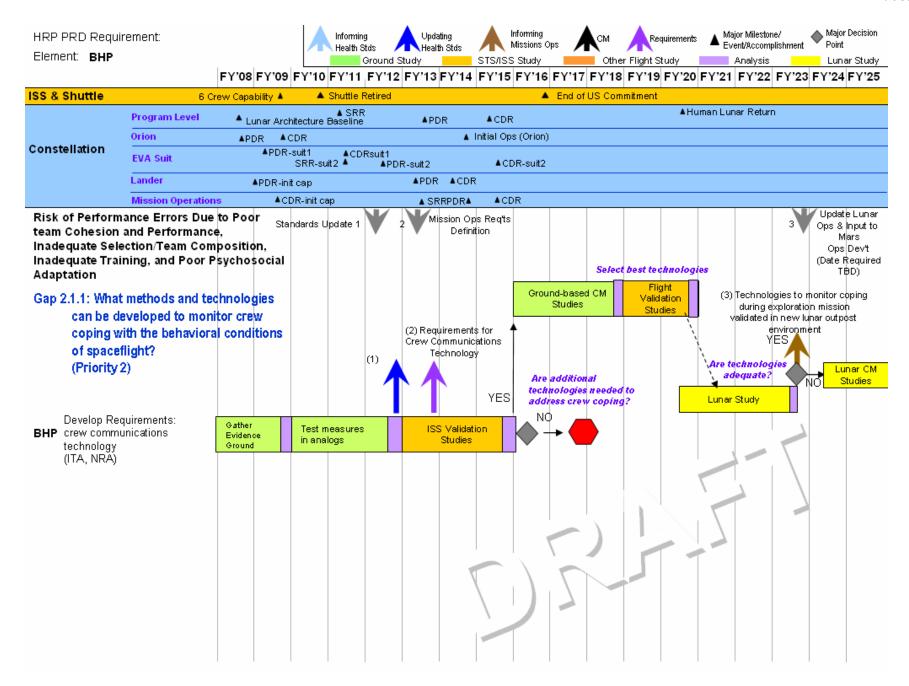
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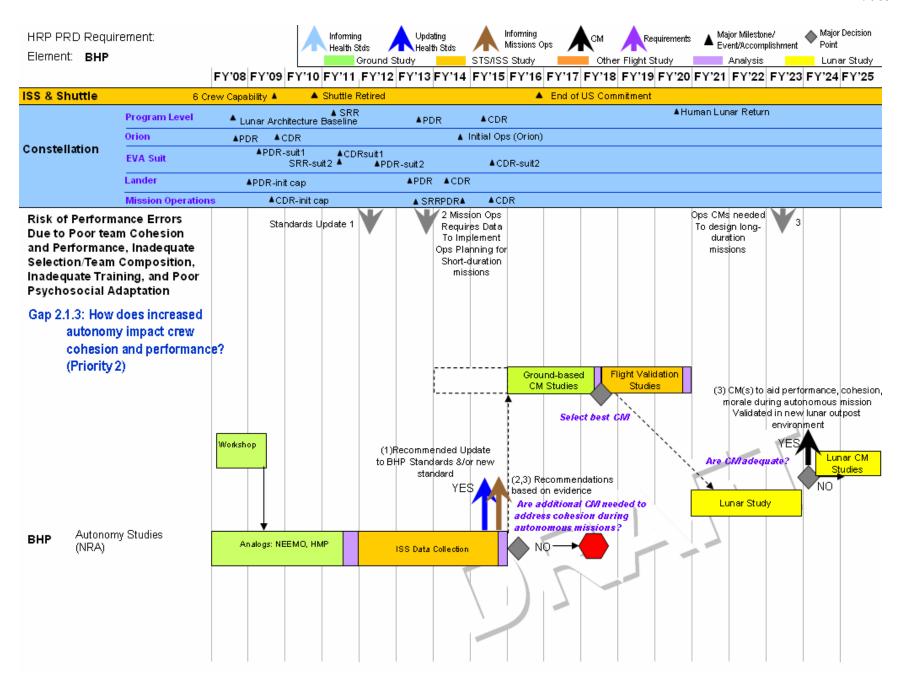


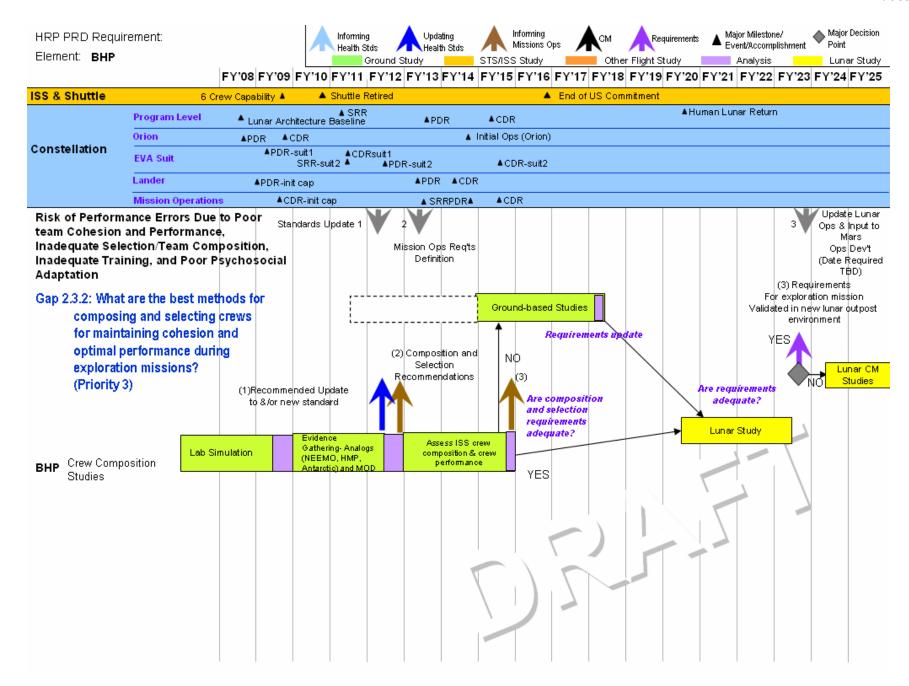
Graphics











23.0 RISK OF CARDIAC RHYTHM PROBLEMS -D X I

Heart rhythm disturbances have been seen among astronauts. Most of these have been related to cardiovascular disease, but it is not clear whether this was due to pre-existing conditions or effects of space flight. It is hoped that advanced screening for coronary disease has greatly mitigated this risk. Other heart rhythm problems, such as atrial fibrillation, can develop over time, necessitating periodic screening of crewmembers' heart rhythms. Beyond these terrestrial heart risks, some concern exists that prolonged exposure to microgravity may lead to heart rhythm disturbances. Although this has not been observed to date, further surveillance is warranted.

Operational Relevance and Risk Context

Missions may be impacted by the occurrence of a clinically-significant dysrhythmia. It is important document whether or not space flight results in clinically significant arrhythmias in astronauts who do not have heart disease.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission. .

Gaps

CV1: Unknown in-flight alterations in cardiac structure and function

CV8: Inability to predict manifestation of sub-clinical or environmentally-induced cardiovascular diseases during spaceflight

Activity:

Integrated Cardiovascular Study

This is a comprehensive study of cardiac function. Data will be obtained pre-flight, inflight (2 weeks, 4 weeks, q 1-2 months), and postflight. Inflight testing will include holter monitoring, 2-d echocardiography, and ambulatory blood pressure monitoring. After completion of this study, the clinical expression of cardiac atrophy during long duration spaceflight will be defined, and its significance for cardiac systolic and diastolic function at rest and during gravitational transitions will be determined. In addition, preliminary information will be obtained regarding ventricular conduction and repolarization that may provide clinical reassurance, or pathophysiologic insight into the risk for cardiac arrhythmias.

HRP-47065

Product/Deliverables:

The initial products are quantification of the extent, time course, and clinical significance of spaceflight-related cardiac atrophy and identification of its mechanisms and functional consequences. If the results indicate that a countermeasure is needed to protect cardiac function, ground-based countermeasures will be evaluated.

Required Delivery Milestone:

The SFHSS cardiovascular standard will be validated / updated in 2013 (needed by FY13 to support mission operations requirements); deliver countermeasure, if necessary, in 2020 (needed as soon as possible to mitigate the risk). Data will feed into lunar validation studies on the lunar surface and a lunar countermeasure will be delivered in 2023 which is required in FY23 for long-duration mission operations.

Required Platforms:

ISS is required for characterization of spaceflight-induced cardiac changes. The bed rest analog may be used for ground-based countermeasure development and efficacy studies prior to validation study using ISS. Further counter-measure development for partial gravity environments may require lunar bed rest analog studies.

Project/Organization Responsible for Implementation of Activity:

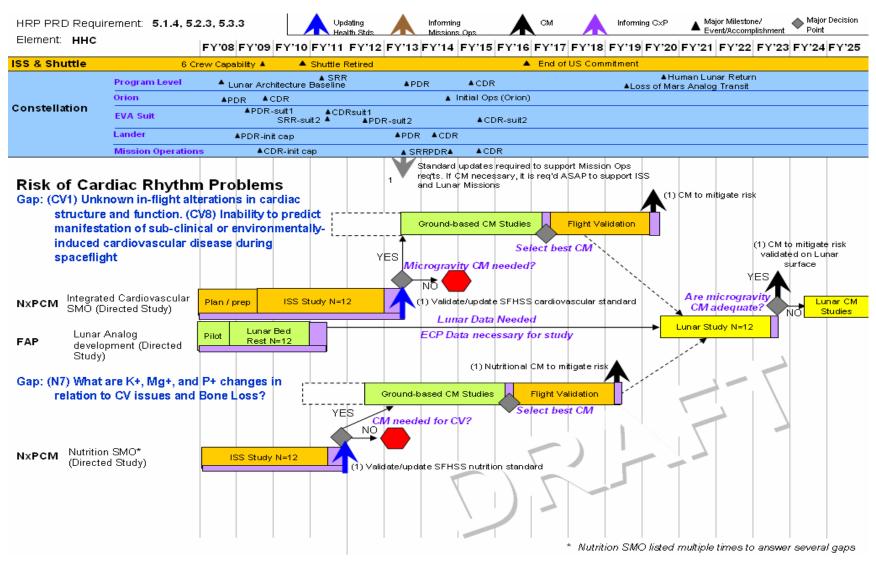
NxPCM - via directed study

N7: What are the K+, Mg+ and P+ changes in relation to cardiovascular issues and bone loss?

Activity

Nutrition Status Assessment – SMO O16E: Nutrition SMO

See Risk of Accelerated Osteoporosis – Gap N7



Graphics

24.0 RISK OF INVERTEBRAL DISC DAMAGE -D X I

Extended exposures to microgravity (and possibly fractional gravity) may lead to an increased risk of spinal nerve compression and back pain.

Operational Relevance and Risk Context

Clinical data indicates that astronauts have a higher incidence of intervertebral disc damage (Postflight? Related to flight?) than the general population. Data should be collected to better define the extent of this problem and to guide design of re-entry and postflight protocols.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

B4: What is the incidence of intervertebral disc damage following spaceflight?

Activity:

Data Mining for Intervertebral Disc Damage

Additional should be to be collected to establish whether the lengthening of the spine during space flight exacerbates the risk for IVD damage with loading. The risk for injury may be greater during the performance of mission tasks in hypogravity, with accelerated g forces from piloting spacecrafts, or with return to gravitational loading on Earth.

Product/Deliverables:

Report of findings, and if the results indicate that a countermeasure is needed to protect against IVD damage, ground-based countermeasure studies may be solicited.

This countermeasure will then inform lunar bed rest studies to determine if microgravity IVD damage countermeasures are adequate for fractional gravity.

Required Delivery Milestones:

Mission operations needs to be informed of data as soon as possible to make any modifications to Orion regarding loads on crew. Validation / updates to the health standard will occur in FY11. If countermeasure development studies are required, a validated countermeasure will be delivered in FY14; which is required as soon as possible to mitigate the risk. Data will feed into lunar

validation studies on the lunar surface and a lunar countermeasure will be delivered in 2023 which is required in FY23 for long-duration mission operations.

Required Platforms:

Retrospective flight data collection and prospective flight data collection plan.

If the data indicate there is damage, the bed rest ground analog is required for the demonstration of microgravity countermeasure efficacy, and ISS is required for countermeasure validation.

Project/Organization Responsible for Implementation of Activity:

NxPCM – directed study

Activity:

Lunar Analog Bed Rest Development

This study is for the development of a lunar analog. These lunar mission simulations may or may not include (~3 day) transit phases between Earth and Moon. While it may be useful to simulate some impacts of (7-14 day) sortic missions, the primary focus will be on longer, outpost missions; thus, simulation durations will generally range up to 90 days.

Product/Deliverables:

Validated lunar analog model

Required Delivery Milestone:

Required Platforms:

This effort is ground-based analog development, developing a lunar analog model. The model will not be validated until lunar surface mission ops begin the in the 2020 timeframe.

Project/Organization Responsible for Implementation of Activity:

Flight Analogs Project (FAP) - via Directed Study

Activity:

Pre/post MRIs for Intervertebral Disc Damage

Additional evidence will be gathered in order to document IVD damage post flight.

Product/Deliverables:

Report of findings, and if the results indicate that a countermeasure is needed to protect against IVD damage, ground-based countermeasure studies may be solicited.

This countermeasure will then inform lunar bed rest studies to determine if microgravity IVD damage countermeasures are adequate for fractional gravity..

Required Delivery Milestone:

Mission operations needs to be informed of data as soon as possible to make any modifications to Orion regarding loads on crew. Validation / updates to the health standard will occur in FY11. If countermeasure development studies are required, a validated countermeasure will be delivered in FY14; which is required as soon as possible to mitigate the risk. Data will feed into lunar validation studies on the lunar surface and a lunar countermeasure will be delivered in 2023 which is required in FY23 for long-duration mission operations.

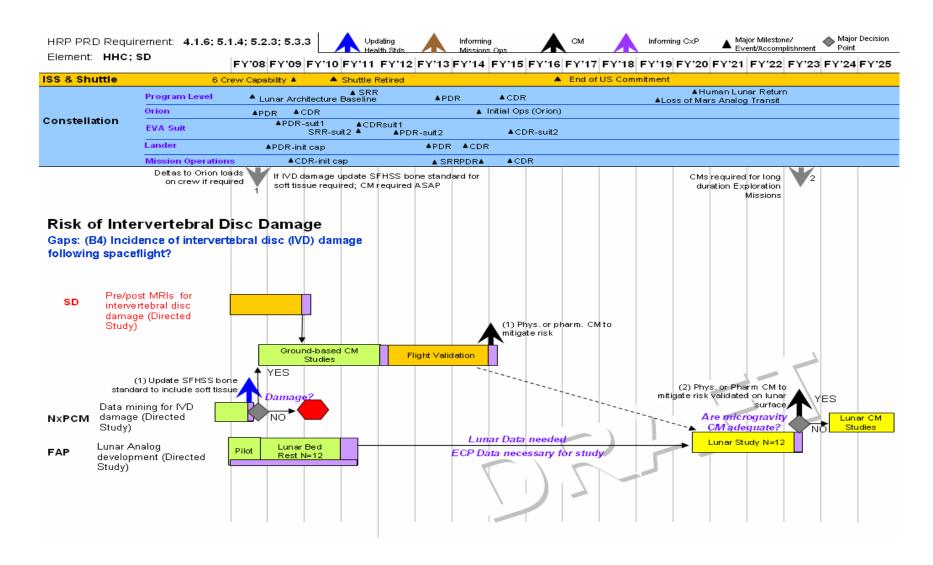
Required Platforms:

ISS crewmember participation is required

The bed rest ground analog is required for the demonstration of microgravity countermeasure efficacy, and later for lunar countermeasure efficacy studies. ISS is required as the Mars transit analog for countermeasure validation.

Project/Organization Responsible for Implementation of Activity:

Space Medicine



Graphics

25.0 RISK OF CREW ADVERSE HEALTH EVENT DUE TO ALTERED IMMUNE RESPONSE -D X I

Human immune function is altered in- and post-flight, but it is unclear if this change leads to an increased susceptibility to disease. Reactivation of latent viruses has been documented in crewmembers, though this reactivation has not been directly correlated with the immune changes or with observed disease. Further research may elucidate whether microgravity exposure impairs the immune system, and whether this change represents a health risk to crews.

Operational Relevance and Risk Context

While there is post-flight evidence to support this risk, in-flight evidence should also be obtained. In-flight immune function data and any clinical correlations should be documented before further research plans are developed. Ground-based work should be conducted using the Antarctic station space flight analog (best available analog for immunity during >6 months. flight) so that ground control data of an appropriate sample size may be obtained. Validation of an analog directly to flight data would be useful for future countermeasures validation. The laboratory findings are to be correlated to clinical findings and follow-up studies are performed to document any latent, long-term effects.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

<u>Gaps</u>

IM1: Lack of in-flight immune data, which is required to determine risk.

IM2: Need formulation of an improved immunology standard for exploration spaceflight.

IM5: Need investigation of individual records of in-flight illness for clarification of timecourse and etiology.

Activities:

1) Flight-Induced Changes in Immune Defenses: 'Immune Function,' DSO 498/SDBI 1498

Shuttle-based study investigating the effects of space flight on 1) neutrophil and monocyte functions (phagocytosis, degranulation, oxidative burst capacity, and expression of surface molecules) and 2) natural-killer cell and lymphokine-activated killer cell cytotoxicity against target cells, and cytokine production

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2) Incidence of Latent Virus Shedding During Space Flight: 'Latent Virus,' DSO 493/SDBI 1493

Shuttle-based study investigating the frequency of latent virus reactivation, latent virus shedding, and clinical disease after exposure to the physical, physiological, and psychological stressors associated with space flight

3) Space Flight-Induced Reactivation of Latent Epstein-Barr Virus: 'Epstein-Barr,' on Shuttle as DSO 493/SDBI 1493 and ISS as E129

Shuttle- and ISS-based study investigates the magnitude of immunosuppression as a result of space flight by 1) analysis of stress hormones, 2) quantitative analysis of EBV replication using molecular and serological methods, and 3) determining virus-specific T-cell immune function

Product/Deliverables:

Final report of findings will be delivered in 2009. Data from these Shuttle-based immune studies will be combined with the ISS-based Integrated Immune SMO to inform and update health standards. If these studies together indicate that a countermeasure is needed, ground-based countermeasure studies will be solicited, then these countermeasures will be validated on ISS.

Required Delivery Milestone:

Final report of findings will be delivered in 2009. Together with Integrated Immune SMO, update health standards in 2011. Validated countermeasures, if required, will be delivered in 2019. All products are required as soon as possible to mitigate this risk.

Required Platforms:

ISS is required to validate the risk (Integrated Immune SMO), to ensure that the data represents space normal and for validation of potential countermeasures. A ground analog (Antarctica, NEEMO, and/or Haughton-Mars) is required for ground studies for countermeasure development.

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

Activity:

<u>Validation of Procedures for Monitoring Crewmember Immune Function: 'Integrated Immune SMO,' SMO 015/SDBI 1900</u>

The objective of this SMO is to develop and validate an immune monitoring strategy consistent with operational flight requirements and constraints. There are no procedures currently in place to monitor immune function or its effect on crew health. Immune dysregulation has been demonstrated to occur during spaceflight, yet little in-flight immune data has been generated to assess whether or not this may be a clinical problem. This SMO will assess the clinical risks resulting from the adverse effects of space flight on the human immune system and will validate a flight-compatible immune monitoring strategy. The correlation between in-flight immunity, physiological

stress and a measurable clinical outcome (viral reactivation) will be determined for long- vs. short-duration space flight.

Product/Deliverables:

Data from this study will be combined with the Shuttle-based immune studies to inform and update health standards. If results indicate that a countermeasure is needed, ground-based countermeasure studies will be solicited and performed. Then these countermeasures will be validated on ISS.

Required Delivery Milestone:

Together with previously mentioned Shuttle-based immune study results, the health standards will be updated in FY11. Validated countermeasures, if required, will be delivered in 2019. All products are required as soon as possible to mitigate this risk.

Required Platforms:

ISS is required to validate the risk (Integrated Immune SMO), to ensure that the data represents space normal and for validation of potential countermeasures. A ground analog (Antarctica, NEEMO, and/or Haughton-Mars) may be used to provide additional data.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

IM3: Lack of ground analog studies, however suitable analogs for immune dysregulation have been identified. Forward work may be expedited using these opportunities.

Activity:

NEEMO Rapid Operational Investigation (ROI): Immune function changes during a spaceflight-analog 10-day undersea mission

This study measures immune functional changes, physiological stress, viral reactivation and viral specific immunity during the NEEMO mission. NEEMO represents a good analog for some aspects of *short-duration* spaceflight on immunity. This study will provide data to compare this ground-based spaceflight-analog to actual flight data. If immune dysregulation is observed in the NEEMO crews that is similar to that observed in flight crews during/following spaceflight, this analog will be validated for some aspects of spaceflight-associated immune dysregulation. This analog will not supersede the program goal to validate a ground analog for long-duration spaceflight and immunity.

Product/Deliverables:

Initial product is completion of the NEEMO study and final report of findings whether the analog is valid for assessing immune responses. If the analog is not valid, additional studies will be solicited to determine a more suitable analog. Results will be combined with other immune studies and if these studies together

indicate that a countermeasure is needed, ground-based countermeasure studies will be solicited and performed. Any countermeasures will be validated on ISS.

Required Delivery Milestone:

Data will feed into knowledge gathered by the Integrated Immune SMO.

Required Platforms:

NEEMO undersea environment is required to assess the validity of the short-duration space analog. Other analog facilities may be required for follow-on studies. A ground analog (Antarctica, NEEMO, and/or Haughton-Mars) is required for development of any needed microgravity countermeasures and ISS is required for their validation.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

Activity:

3D Tissue Analogs for the Study of Varicella-Zoster Virulence and Infectivity

This study is concerned with determining if: VZV is alive, active and has the potential to spread. VZV may assume increased virulence and/or live virus numbers in microgravity. This study will demonstrate the sensitivity of the model and provide an operational deliverable in the form of a reliable test for live quantifiable virus.

Product/Deliverables:

Initial product is completion of the ground-based study and final report of findings. Results will be combined with other immune studies and if these studies together indicate that a countermeasure is needed, ground-based countermeasure studies will be solicited and performed. Any countermeasures will be validated on ISS.

Required Delivery Milestone:

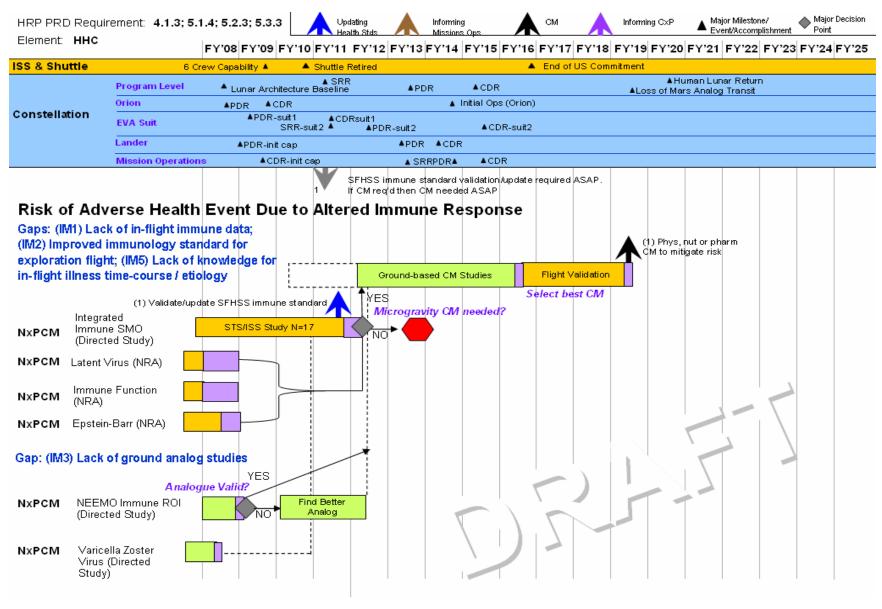
Study completion by 2008. Data will feed into knowledge gathered by the Integrated Immune SMO.

Required Platforms:

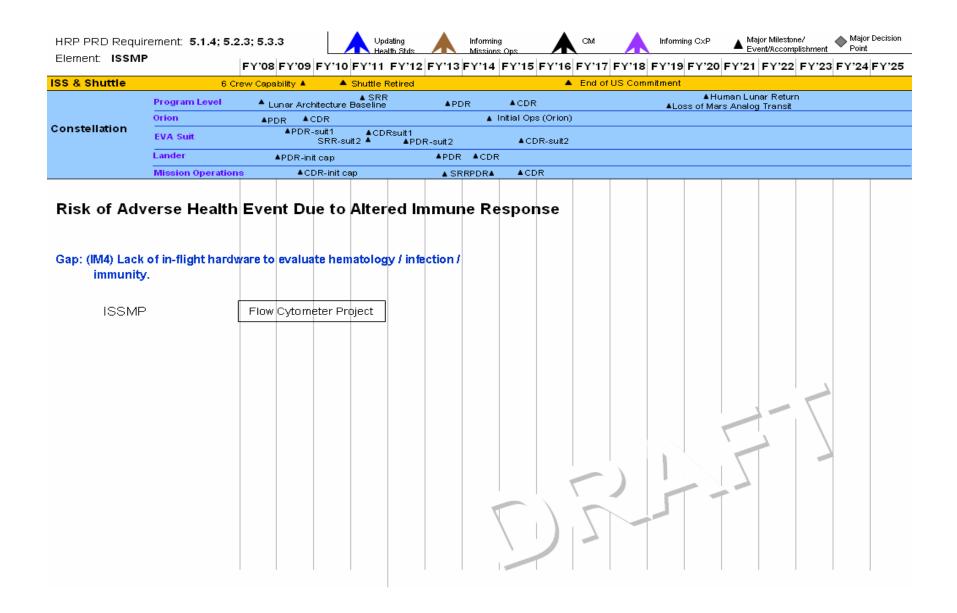
Ground-based laboratory is required.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study



Graphics



26.0 RISK OF IMPAIRED ABILITY TO MAINTAIN CONTROL OF VEHICLES AND OTHER COMPLEX SYSTEMS -D X I

It has been shown that long-duration Spaceflight alters sensorimotor function which manifests as changes in locomotion, gaze control, dynamic visual acuity, and perception. These changes have not specifically been correlated with real time performance decrements. The possible alterations in sensorimotor performance are of interest for Mars missions due to the prolonged microgravity exposure during transit followed by landing tasks. This risk must be better documented and NS changes must be better correlated with performance issues.

Operational Relevance and Risk Context

New evidence regarding landing performance indicates that research into these types of issues is not a high priority for Shuttle or ISS. However, since Mars operational scenarios are still TBD, it is agreed that the ISS should be utilized to gather the data required to define the research that might be needed to enable future Mars mission operations. Therefore, this risk is considered to have a higher priority than the others within the sensorimotor discipline. Spaceflight data should be collected (RMS, SSRMS, docking, glove box ops, Soyuz landings, etc.). In addition, performance related to neurosensory dysfunction should be used to determine the need for further research and countermeasure development.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Important to Quantify and Reduce Prior to the Mars Mission.

Gaps

SM1: Relationship between the mode of in-flight exercise and post-flight sensorimotor performance

Activity:

Sensorimotor Performance Data Mining

It is proposed that the type and amount of in-flight exercise performed by crewmembers may influence post-flight disturbance in balance and locomotion. Exercise logs for both US and Russian crewmembers will be evaluated to determine the relationship between the types of in-flight exercise performed and post-flight sensorimotor performance.

Product/Deliverables:

Initial product is space normal data from a data review activity. If results indicate that a microgravity countermeasure can improve sensorimotor performance, ground based studies may be solicited and performed, and the best

countermeasures validated using ISS flight studies. Data from the countermeasure flight validation studies will feed into lunar surface studies.

Required Delivery Milestones:

Report of findings will be delivered in 2009 and the SFHSS sensori-motor standard will also be validated / updated at that time; if necessary a countermeasure will be delivered in FY17. Both products are required in FY13 to support mission operations requirements development.

Required Platforms:

Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data review.

A ground analog is required for the demonstration of microgravity countermeasure efficacy, and ISS is required for potential countermeasure validation.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

SM2: What is the time course of recovery of sensorimotor function after long-duration space flight?

Activity:

Sensorimotor Performance Recovery Data Mining

After long -space flights, astronauts require time to return to pre-flight sensorimotor performance. This study will compile the recovery data from previous long-duration astronauts to determine the average amount of time that is required for sensorimotor function recovery.

Product/Deliverables:

Initial product is space normal data from a data mining activity. Results will be provided to mission operations.

Required Delivery Milestone:

Mission operations will be informed of the results and updated health standard will be delivered in 2009. Both products are required in FY13 to support mission operations requirements development.

Required Platforms:

Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

SM4: Correlate previous performance data with clinical observations

Activity:

Performance Data Mining

This study will compile data recorded from previous missions regarding ISS EVAs. The purpose of this data mining activity is to gain additional operational data. Lessons learned from this analysis can be applied to the Constellation Program to ensure that the evidence for sensorimotor changes in crew performance as a result of space flight is thoroughly assessed.

Product/Deliverables:

Initial product is space normal data from a data mining activity. If results indicate that a microgravity countermeasure is needed for sensorimotor performance, ground-based studies will be solicited and performed, and the best countermeasures validated using ISS flight studies.

Required Delivery Milestone:

Report of findings will be delivered in 2009 and the SFHSS sensori-motor standard will also be validated / updated at that time; if necessary a countermeasure will be delivered in FY17. The countermeasure is required as soon as possible to mitigate the risk for current crew and the standard update is required in FY13 to support mission operations requirements development.

Required Platforms:

Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study.

A ground analog may be required for the demonstration of microgravity countermeasure efficacy. ISS is required as the Mars transit analog for countermeasure validation.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

SM5: What are the effects of disorientation and inter-individual differences on supervisory control, docking, RMS, etc?

Activity:

Performance Data Mining

This study will compile data recorded from previous missions regarding manual control and landing. The purpose of this review is to gain additional operational data and insight regarding Shuttle landings to determine the multi-factorial causes that led to the landing outcomes. Lessons learned from this analysis can be applied to the Constellation Program to ensure that the evidence for sensorimotor changes in crew performance as a result of space flight is thoroughly assessed. Data will also be

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gathered from available data from RMS operations, EVAs and Shuttle/Soyuz docking operations relevant to manual control.

Product/Deliverables:

Initial product is space normal data from a data mining activity. If results indicate that a microgravity countermeasure is needed for sensorimotor performance, ground-based studies will be solicited and performed, and the best countermeasures validated using ISS flight studies.

Required Delivery Milestone:

Report of findings will be delivered in 2009 and the SFHSS sensori-motor standard will also be validated / updated at that time; if necessary a countermeasure will be delivered in FY17. The countermeasure is required as soon as possible to mitigate the risk for current crew and the standard update is required in FY13 to support mission operations requirements development.

Required Platforms:

Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study.

A ground analog may be required for the demonstration of microgravity countermeasure efficacy. ISS is required for countermeasure validation.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

SM6: Need to perform a seated Manual/Visual performance assessment after long-duration spaceflight.

Activity:

Head-eye Coordination during Simulated Orbiter Landings

The aim of this study is to obtain basic data on the characteristics of head and eye movements during simulated Orbiter landings. This information will be used to determine landing tasks that may induce spatial disorientation. In addition, two paradigms will be used to model spatial disorientation due to microgravity exposure: 1) long-duration hyper-gravity exposure in a centrifuge, and 2) galvanic vestibular stimulation (GVS). Preliminary results suggest that post-centrifuge disorientation, and per-GVS exposure, generate symptoms of spatial disorientation comparable to space flight. Simulated landings in the VMS will be performed both post-centrifugation and with GVS, to test the hypothesis that spatial disorientation diminishes head-eye coordination and landing performance. This may serve as a model for the deterioration in pilot performance during reentry, and provide a training regimen to allow commanders and pilots to experience spatial disorientation in a simulator.

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Product/Deliverables:

Initial product is completion of ground-based study and a validated model of spatial disorientation (SD) due to microgravity exposure that can be used to familiarize shuttle pilots with SD symptoms during simulated landings, as well as a training tool to improve landing performance after space flight.

Required Delivery Milestone:

Complete study by 2009

Required Platforms:

Ground based study

Project/Organization Responsible for Implementation of Activity:

NxPCM - via NRA

Activity:

Manual/Visual Control Study (Phase I & II) – TBD

This study in preparation will be conducted as a pre- and post-flight study using long-duration ISS crewmembers.

Product/Deliverables:

Initial product will be completion of an ISS pre- and post-flight study to determine seated manual/visual control performance (i.e., landing a spacecraft). If study results determine that a countermeasure is necessary, ground-based studies will be solicited and performed. The best countermeasures will be selected and validated on ISS.

This countermeasure will then inform lunar bed rest studies to determine if microgravity manual/visual control performance countermeasures are adequate for fractional gravity.

Required Delivery Milestone:

Complete study and report findings will be delivered by FY13. If countermeasures are needed, validated countermeasure(s) will be delivered to mission operations by FY20. This potential countermeasure is required as soon as possible to mitigate the risk.

Data will feed into lunar countermeasure validation studies with delivery of lunar countermeasure in FY23 which are required for long-duration lunar missions.

Required Platforms:

ISS is required for countermeasure validation. The bed rest ground analog is required for the demonstration of microgravity countermeasure efficacy.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

SM3: What is the appropriate rehabilitation protocol for sensorimotor function?

Activity:

The HHC Element will collaborate with the Space Medicine Division (SD), specifically the Astronaut Strength, Conditioning and Rehabilitation (ASCR) group to identify the appropriate rehabilitation protocol for sensorimotor function.

Product/Deliverables:

Required Delivery Milestone:

Required Platforms:

Project/Organization Responsible for Implementation of Activity:

HHC and ASCRs

SM10: There are no stated acceptable ranges of cognitive and psychomotor performance.

Activity:

The HHC Element will negotiate with the Behavioral Health and Performance (BHP) Program Element to develop a multi-factorial cognitive risk assessment.

Product/Deliverables:

Required Delivery Milestone:

Required Platforms:

Project/Organization Responsible for Implementation of Activity:

BHP

SM13: Incorporate vestibular assessments within the in-flight periodic exams.

SM15: Need to adopt a multi-disciplinary approach to identify crewmembers at greatest risk of falls; also need to implement and track directed rehabilitation

SM16: Need to insure that astronauts at risk of falls are accompanied until the risk diminishes to acceptable levels.

SM17: Require an astronaut post-flight fall risk assessment that should be a coordinated effort between crew surgeons, ASCRs and discipline researchers.

Activity:

The HHC shall negotiate with SD to: determine whether vestibular assessment should be incorporated into in-flight periodic exams; develop a multi-disciplinary approach to identifying crewmembers at greatest risk of falls, and to implement and track directed

rehabilitation; insure that astronauts at risk of falls are accompanied until risk diminishes to acceptable levels; and develop an astronaut post-flight fall risk assessment that should be a coordinated effort between crew surgeons, ASCRs and discipline researchers.

Product/Deliverables:

Required Delivery Milestone:

Required Platforms:

Project/Organization Responsible for Implementation of Activity:

SD

SM11: Need to provide alternate sources for spatial orientation.

Activity:

Advanced Displays for Efficient Training and Operation of Robotic Systems

Product/Deliverables:

Required Delivery Milestone:

Required Platforms:

Project/Organization Responsible for Implementation of Activity:

SHFH - NSBRI NRA

Activity:

Modeling and Mitigating Spatial Disorientation in Low-Gravity Environments

Product/Deliverables:

Required Delivery Milestone:

Required Platforms:

Project/Organization Responsible for Implementation of Activity:

SHFH - NSBRI NRA

SM12: Need to develop standards for spaceflight cockpit control displays and inputs.

Activity:

This work needs to be completed by the Human Environmental Factors Division

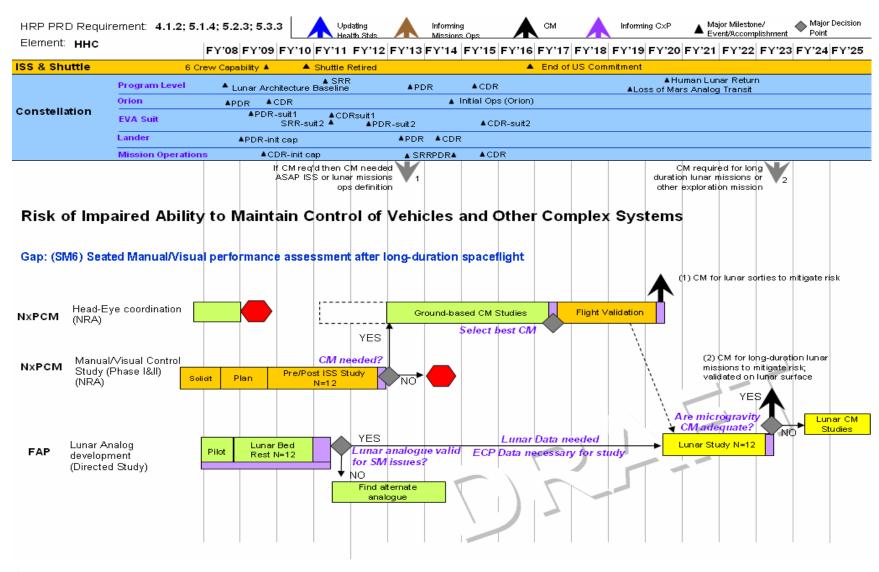
Product/Deliverables:

Required Delivery Milestone:

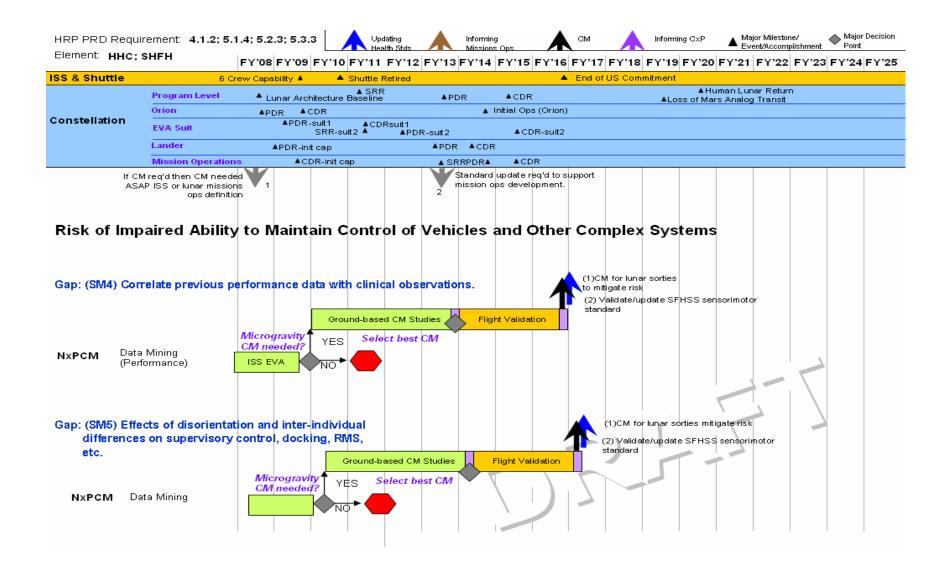
Required Platforms:

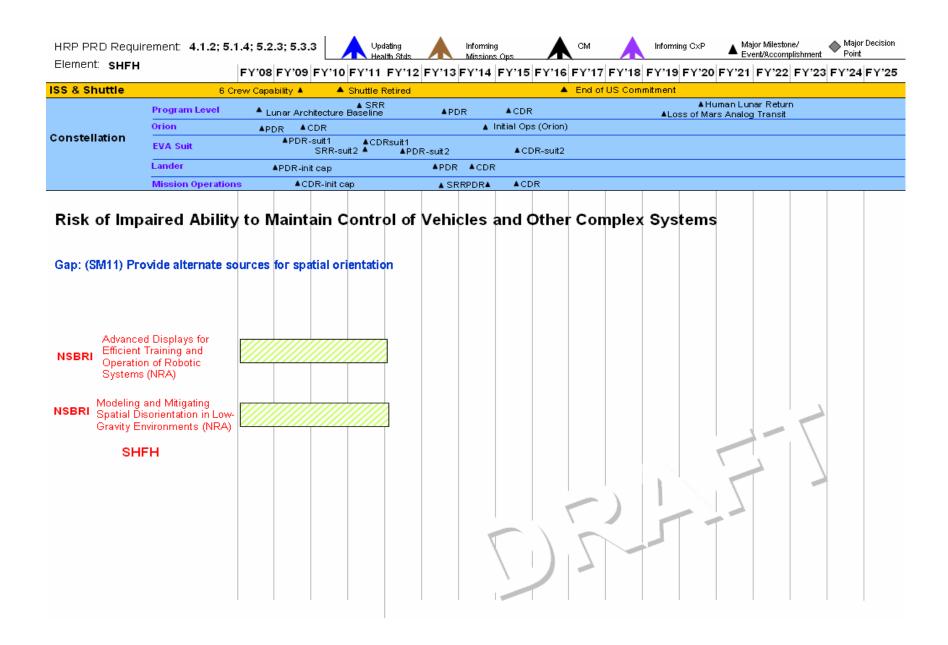
Project/Organization Responsible for Implementation of Activity:

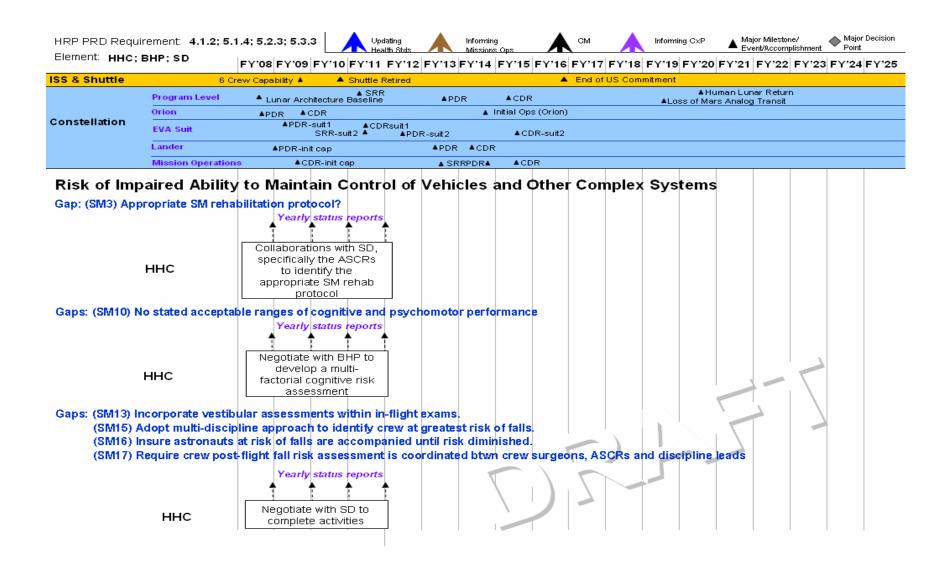
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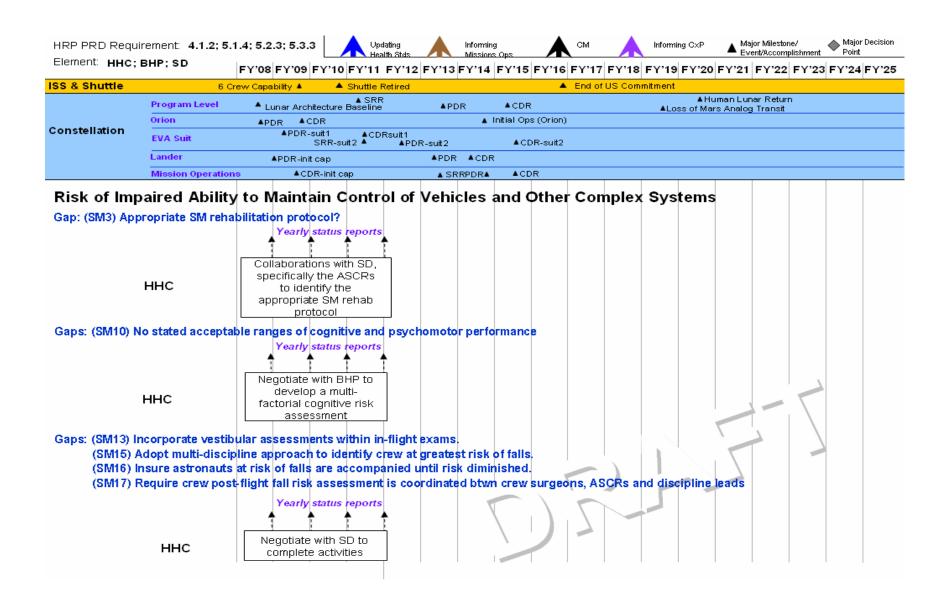


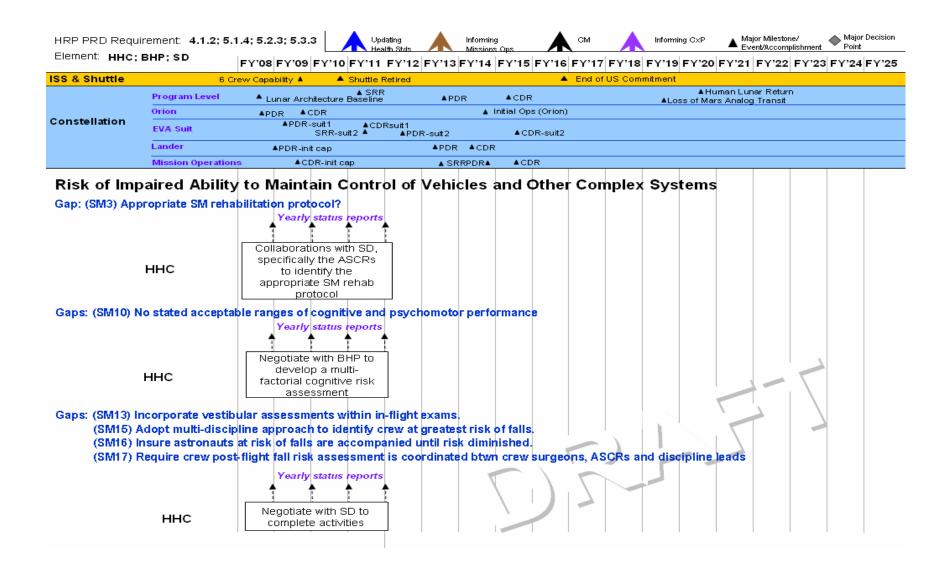
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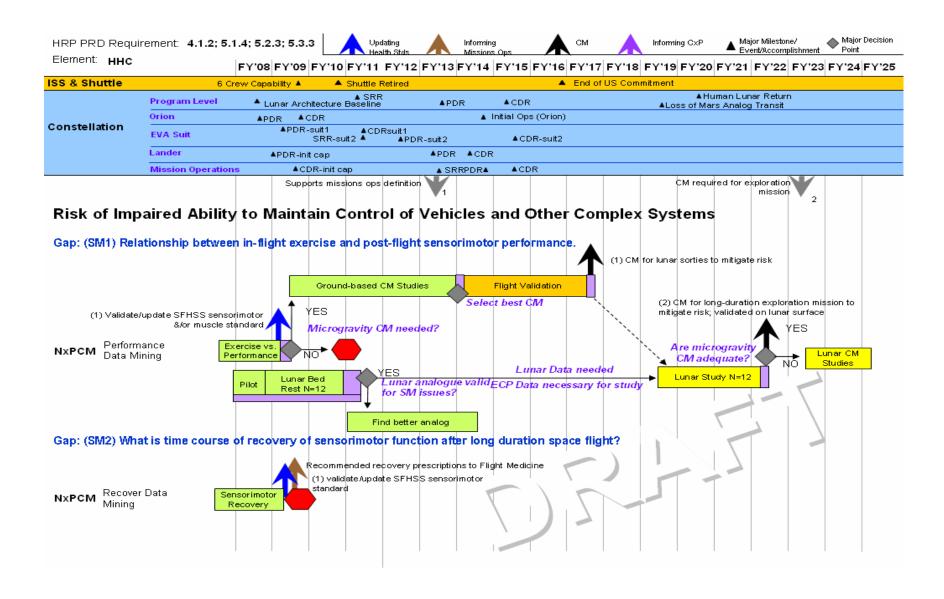












27.0 RISK OF PERFORMANCE ERRORS DUE TO SLEEP LOSS, CIRCADIAN DESYNCHRONIZATION, FATIGUE, AND WORK OVERLOAD -D X D

Fatigue occurs during spaceflight and will jeopardize health and performance. This risk may be influenced by artificial and transmitted light exposure, individual vulnerability to sleep loss and circadian dynamics, and work/sleep schedules. Efforts are needed to improve sleep hygiene, and to identify and improve conditions that interfere with sleep quality. Research areas may include: development of a self-assessment tool for cognitive function and fatigue, light therapy for phase shifting, alertness and mood disorders, and other means to improve sleep quality and reduce fatigue.

Operational Relevance and Risk Context

Research demonstrates that aspects of the spaceflight environment may disrupt circadian rhythms and reduce sleep; anecdotal evidence from spaceflight reveals that fatigue and work overload can also occur. Ground studies illustrate that lack of adequate amounts of good quality sleep, as well as performance operations during times of fatigue or circadian desynchronization, can adversely affect performance capability and safety.

Lunar surface activities will be both strenuous and fatiguing, and will likely involve some shift work. Furthermore, fatigue is a risk factor for the other two Behavioral Health and Performance Risks (Risk of Performance Errors Due to inadequate Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation; Risk of Behavioral and Psychiatric Conditions.) It is therefore essential to develop countermeasures for issues related to sleep loss, fatigue, circadian desynchronization and work overload. BHP research activity aims to assess this risk as well as provide adequate standards and countermeasures for Exploration Missions.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Desirable to Quantify and Reduce Prior to the Mars Mission.

Gaps

BHP 1.1.1 What are the best measures and tools to use for assessing decrements in cognitive function due to fatigue and other aspects of spaceflight? (Priority 1)

A correlation between fatigue and performance in spaceflight has not been documented. A means to objectively assess cognitive decrements and provide information during mission operations to the crew surgeon and astronaut may be helpful.

Activity:

Refine and Validate Three Minute Performance Vigilance Task (PVT)

Validate in analogs (NEEMO, HMP, PML); field test on STS; validate for spaceflight on ISS. Concurrently enhance tool so it serves as a self-assessment measure for the Astronaut and provides feedback to flight surgeons during autonomous missions.

Product/Deliverables:

- 1) PVT/Cognitive Assessment Tool
- 2) Update Standards (if applicable)

Required Delivery Milestone:

Field test on STS in 2009; Deliver in 2013; Required by 2014 for Missions Ops implementation

Required Platforms:

Analogs include: NEEMO, Phoenix Mars Lander (PML), Haughton Mars Project (HMP), Russian Chamber Study (105-day)

Data gathered on NEEMO to provide normative data for spaceflight

Field testing and initial validation anticipated on STS. In-flight validation of tool to continue on ISS. Requires spaceflight because of sleep loss and fatigue issues related to microgravity and other spaceflight environmental factors, and to ensure the test is appropriate for the spaceflight environment.

Project/Organization Responsible for Implementation of Activity:

Directed Study, with NSBRI

Activity:

Refine and Validate Fatigue Meter

A physical meter that measures environmental (e.g., light exposure, noise) and physiological signals (e.g., sleep wake activity) to determine individual fatigue levels and provide the user (e.g., astronaut/flight surgeon, MOD/ground support) with feedback about potential decrements in performance ability. Such a measure will also provide information on circadian phase to indicate levels of potential risk due to fatigue.

Product/Deliverables:

- 1) Validated meter for use in spaceflight
- 2) Update to Standards, if applicable

Required Delivery Milestone:

Delivered by 2013; Required by 2014 for Mission Ops implementation

Required Platforms:

Identify tools being used in military operations. Validate in analogs including: Phoenix Mars Lander (PML), Haughton Mars Project (HMP) and Russian Chamber Study (RC) – 105-day. Requires the ISS because of sleep-related issues associated with microgravity, and to ensure the instrument is appropriate/feasible for spaceflight environment; Involves collaboration with EPSP.

Project/Organization Responsible for Implementation of Activity:

Directed Studies (PML, HMP) with NSBRI and possible NRA

BHP 1.1.5 How is performance in spaceflight affected by sleep loss, circadian desynchronization, fatigue and work overload? (Priority 1)

Data needs to be collected so that cognitive performance in the spaceflight environment can be assessed, and appropriate countermeasures developed, as necessary, and/or policies/standards enforced.

Activity:

Cognitive Performance Studies

Collect performance data using PVT (a hand-held instrument that uses a three-minute psychomotor vigilance test of speed and accuracy), augmented with self-assessment interface that provides real-time feedback to users regarding cognitive performance.

Collect data during field test of PVT on STS, and validate PVT on ISS. If data collected in-flight reveals that additional measures are needed to address cognitive function, beyond those already developed/being developed, ground based studies will commence and be followed by a phase of inflight validation and lunar studies.

Product/Deliverables:

- 1) Recommendations to Mission Ops regarding fatigue and cognitive performance, based on evidence gathered using the PVT
- 2) Update to Standards

Required Delivery Milestone

Data collection to begin on STS in 2009; Recommendations delivered in 2013. Recommendations required by 2013 for Mission Ops Requirements Definition.

Required Platforms:

Data collection to begin during field testing of instrument on STS; Data collection to then continue on ISS; Requires the ISS because aim of the study is to characterize cognitive performance as a result of the spaceflight environment, including the sleep-related issues associated with microgravity. This effort involves collaboration with HHC and SHFH, with BHP serving as lead.

Project/Organization Responsible for Implementation of Activity:

Directed Study with NSBRI

BHP 1.3.1: How can physical and cognitive workloads be optimally managed in space relative to fatigue and recovery? (Priority 2)

BHP 1.3.3: What duration of physiological sleep is needed to recover from chronic partial sleep loss, slam shifting, or high tempo sustained operations? (Priority 2)

While the evidence is largely anecdotal, strict adherence to timelines has been reported to be fatiguing and stressful for astronauts. Furthermore, individuals on analog missions where there are unusual light cues (i.e. twenty four hour sunlight in the Arctic) have reported that they continue to work for hours on end without feeling a need for sleep, a potential concern since lack of sleep and fatigue can affect performance. In future space missions to the Moon or Mars, crewmembers will be given more autonomy to plan and carry out their activities due to the long distances involved and the tasks that will be needed to explore a planetary surface, and they will also be exposed to light cues unlike those on Earth. Recommended optimal work rest schedules need to be provided so that crews can make informed decisions around work and rest.

Activity:

Develop Optimal Work Rest Schedules

Refine mathematical models to optimize schedules and target countermeasures for sleep strategies, and to identify the best countermeasure application and timing. Ground based studies to investigate sleep dose recovery requirements. Data mining/collection of performance in flight, in conjunction with subjective assessment of sleep/recovery/work schedules, and actigraphy data. Evaluation of preferred work-rest schedules during the high- and low- autonomy conditions identified in Autonomy Study (Team Risk, Gap 2.1.3)

Product/Deliverables:

- 1) Optimal work-rest schedules to prevent mental and physical fatigue during any operational tempo.
- 2) Recommendations to be incorporated into Spaceflight Human Systems Standards.
- 3) Input for developing an integrated mathematical model to optimize schedules, countermeasures, and performance (see Gap 1.1.3). The models are based on overall risk for the crew as well as performance risk tailored for individual astronauts. Recommendation for crew scheduling controls to mission designers.

Required Delivery Milestone:

Update Standard 2012. Requirements for Mission Ops due by 2013. Study completed 2014 (status provided in 2013 with subsequent updates.)

Required Platforms:

Ground studies include analogs: NEEMO, PML, HMP, and MOD flight controllers. Data collection requires BHP/MOD/CB/SD/SHFH collaboration. Requires the ISS because of sleep-related issues associated with microgravity, and to accurately emulate the spaceflight high-tempo, remotely scheduled and controlled environment. The ISS will emulate the transit environment to Mars.

Project/Organization Responsible for Implementation of Activity:

NRA

BHP 1.3.2: How can sleep loss be administratively controlled? (Priority 2)

Despite medication use, sleep loss does occur during spaceflight, with some crewmembers reporting minimal amounts of sleep, particularly prior to conducing critical mission tasks. Many factors can affect sleep quality and quantity in the spaceflight mission environment including high noise levels, shifting schedules, high tempo workloads, thermal temperature changes, microgravity adjustment, and close proximity to others. Flight surgeons have requested information that can aid individual astronauts on improving their sleep quality and quantity during spaceflight. Given the complexity of spaceflight missions, and the effects of sleep loss on fatigue and performance, such information will be instrumental for not only crewmembers, but also their families, ground support teams, and other medical personnel regarding strategies to improve sleep quantity and quality. Information will help inform current standards as well as those for future missions.

Activity:

Sleep Quality Questionnaire

Data collection from crews returning from flight regarding their sleep quality on-orbit, and in comparison to their terrestrial sleep and during various training activities. This questionnaire is designed to assess what factors effect sleep quality and quantity and seeks suggestions regarding strategies for improving sleep on-orbit for future flyers.

Product/Deliverables:

- 1) Educational materials for astronauts, management and ground support on strategies for improving sleep quality and quantity during human spaceflight missions.
- 2) Recommendation for standard to protect sleep, minimize fatigue, and maintain performance.

Required Delivery Milestone:

Standards update required by 2012. Recommendations for policies to be delivered by 2013 for Lunar Operations Mission Design. Requirements for Lunar Habitat due by 2023, delivered by 2013.

Required Platforms:

Primarily ground effort. Once policy changes are implemented, data collection to assess and evaluate effectiveness of changes. This includes a data mining effort in collaboration with CB and Med Ops.

Project/Organization Responsible for Implementation of Activity:

Directed Study

BHP 1.2.2 What are the performance risk/benefits of specific sleep/wake medication during sleep inflight? (Priority 2)

Flight surgeons have requested an electronic database that will make information regarding the effects of sleep-wake medications readily available to them.

Activity:

Develop Electronic Sleep Wake Medication Database

Literature review regarding the effects of sleep medication, including performance, safety, and potential side effects. Literature should also indicate potential effects if user is awakened shortly after consuming sleep medication.

Product/Deliverables:

Electronic Sleep Medication Database

Required Delivery Milestone:

Database to be delivered in 2008, with subsequent updates every four years; Database due by 2013 for Mission Ops Requirements Definition

Required Platforms:

This effort, at this time, is primarily data mining and building the database. Results from the planned Crew Quarters Sleep/Wake medications study (see Gap 1.2.3) will provide additional information on performance effects following medication use. Involves collaboration with HHC/ Pharmacology and ExMC.

Project/Organization Responsible for Implementation of Activity:

BHP Directed study

BHP 1.2.3 What are the best individual dosing requirements/protocols for sleep and alertness medications during spaceflight? (Priority 2)

Activity:

Crew Quarters Sleep Medication Study

The "Crew Quarters Study" is a ground based study to test commonly used sleep/wake medications on the presence, magnitude and time course of cognitive performance deficits in astronauts prior to spaceflight missions. The study will determine also if there are sedating carry over effects on neurobehavioral functions upon abrupt premature termination of sleep in order to simulate an emergency situation. Astronauts sleep overnight in the Crew Quarters facility at Johnson Space Center after consuming their choice/dose of sleep medication. Performance and safety effects will be evaluated at different times following the consumption of the medication.

Product/Deliverables:

- 1) Requirements for best operational approach for utilizing sleep/wake medications during training/flight.
- 2) Individualized Recommendations for Sleep/Wake Medications.

Required Delivery Milestone:

Ground study completed in 2010; Requirements and Recommendations validated in flight and delivered to Mission Ops by 2013; Due for Mission Ops Requirements Definition by 2013

Required Platforms:

This effort is primarily ground studies using astronauts. Requires validation on ISS, with CEV and surface operations validation on moon. Involves collaboration with HHC/Pharmacology and ExMC as well as SD and CB.

Project/Organization Responsible for Implementation of Activity:

Space Medicine – BHP Directed study

BHP 1.1.2 Does sleep loss continue on long duration missions or is there adaptation? (Priority 3)

Previous spaceflight studies have revealed that space crews are at times not sleeping for the duration of their scheduled sleep period. Crewmembers experience frequent shifts in their sleep/wake schedules, and in addition, various environmental factors affect sleep quality and quantity. Studies have shown that self-report of just how much sleep one is actually getting can be inaccurate. Therefore, in order to accurately assess to what degree sleep is disrupted on-orbit, an unobtrusive, objective measure of sleep-wake activity is needed.

Objective sleep data during the course of a mission provides important operational feedback for the astronaut as well as the flight surgeon, particularly prior to performing critical mission tasks.

Activity:

Sleep/Wake Activity Study

Collect inflight data using an Actigraph watch to objectively document sleep and wake times, and a sleep log for subjective information on countermeasure use, and factors related to sleep loss during spaceflight. Data are collected during shuttle and ISS missions to quantify spaceflight and light-exposure-related sleep disturbances, examine sleep shift schedules on sleep, and use of countermeasures (i.e. lighting, medication).

Product/Deliverables:

- 1) Operational use of Actigraph during missions (MRID).
- 2) Update to Standards.
- 3) Recommendations to Mission Ops based on evidence.

Required Delivery Milestone:

Tool to be delivered for ISS operations by 2011 (or before if possible); recommendations based on evidence delivered and due for Lunar Mission Ops by 2013; actigraph technology required prior to 2014 for Lunar Operations Mission Design, unless functions of actigraph are fulfilled by the fatigue meter. If so, actigraph operations to cease once fatigue meter becomes operational. If not, actigraph operations to continue and follow-on validation and optimization for Mars Missions to occur in lunar ops.

Required Platforms:

Requires the STS and ISS because of sleep-related issues associated with spaceflight. Requires continued participation by STS crews because of the wide variation across missions. Requires ISS because to date, relatively little is known about sleep quantity and quality on the ISS. Study provides information important for exploration planning. There is a high acceptability for participating in this study and high compliance among the astronauts participating in study.

Project/Organization Responsible for Implementation of Activity:

NRA

BHP 1.1.3 How can individual astronauts' vulnerabilities to sleep loss and circadian rhythm disruption best be determined? (Priority 3)

Activity:

Develop and Integrate Mathematical Models

Literature review to determine objective predictors of sleep vulnerabilities and resistances. Mathematical model development incorporating individual vulnerabilities, identification of the best countermeasure application, timing, etc., to ensure performance during critical mission tasks. Verification of objective predictors (e.g., biomarkers) of vulnerabilities to sleep loss and its effects in spaceflight. Workshop to enhance collaborations between investigators and integration of models.

Product/Deliverables:

Integrated mathematical model to determine optimal timing of countermeasures to ensure performance, based on individual vulnerabilities to sleep loss and circadian desynchronization.

Required Delivery Milestone:

Required and delivered by 2013 for Lunar Mission Ops Requirements Definition; it is anticipated that integration efforts will continue every two years in preparation for Lunar Habitat Mission Ops Implementation. Requirements due by 2013 for Lunar Missions and 2023 for Lunar Habitat.

Required Platforms:

This effort is primarily ground studies, and data mining effort.

Project/Organization Responsible for Implementation of Activity:

NSBRI

BHP 1.2.1 How can light be used to optimally minimize circadian problems in space? (Priority 3)

Preliminary studies indicate that light exposure can correct difficulties in sleep patterns that occur with shift work, jet lag and sleep disorders. The timing, duration, and wavelength of the light impact countermeasure effectiveness. Acute and long-term safety and performance effects should be evaluated.

Activity:

Studies to Determine Optimal Light Spectrum

These studies will evaluate safety and performance to determine whether blue-enriched fluorescent light can be used to regulate circadian rhythm in the low-lighting levels common to spacecraft. If successful, then onboard artificial lighting systems may serve the dual purpose of maintaining circadian entrainment while providing illumination that supports vision.

Product/Deliverables:

- 1) Hardware Requirements Lunar Lander lighting spectrum.
- 2) Recommended update to Standards.
- 3) Requirements on best operational approach for utilizing light for circadian entrainment/fatigue.
- 4) Hardware Requirements Lunar Habitat lighting spectrum.
- 5) Requirements to maintain alertness on Exploration Missions

Required Delivery Milestone:

Hardware Requirements due by 2012 for Lunar Lander design; hardware requirements for Lunar Lander to be delivered in 2012. Standards update by 2012.

Requirements on the best operational approach for utilizing light in-flight (duration, timing, etc.), due by 2013 for Mission Ops implementation. Research activity to be completed by 2014.

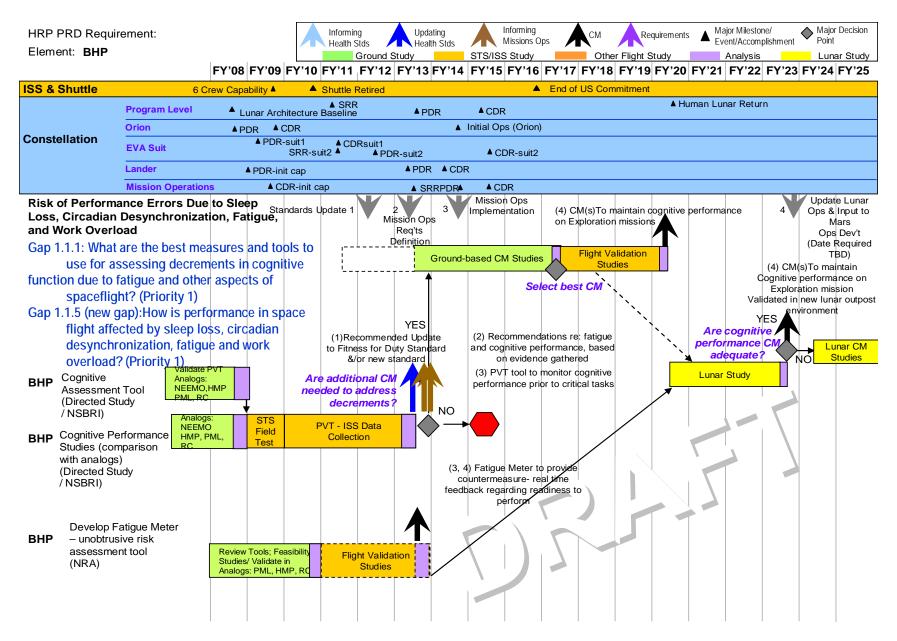
Hardware updates for the Lunar Habitat to be delivered by 2020.

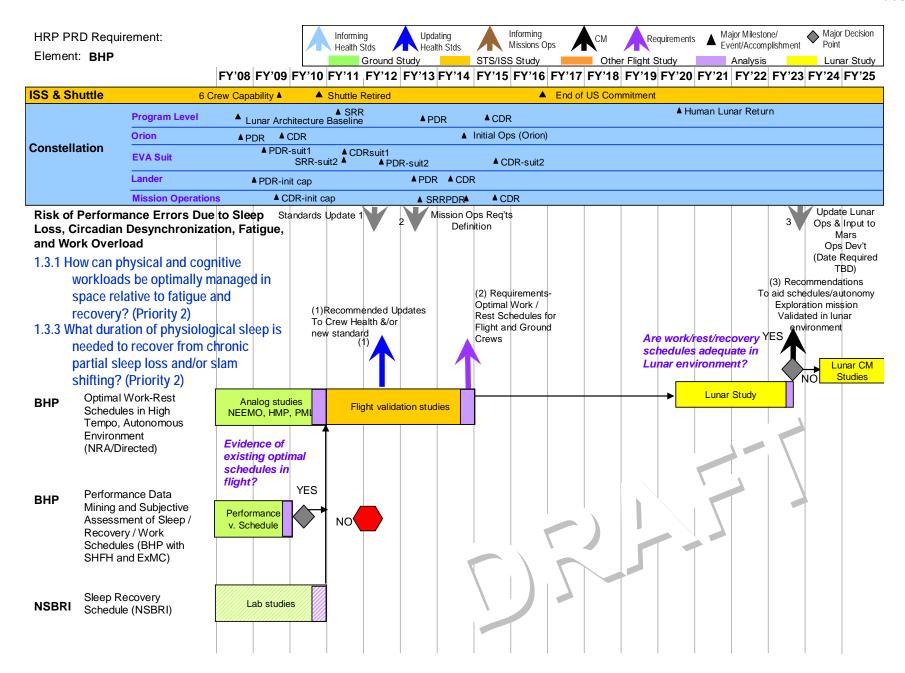
Required Platforms:

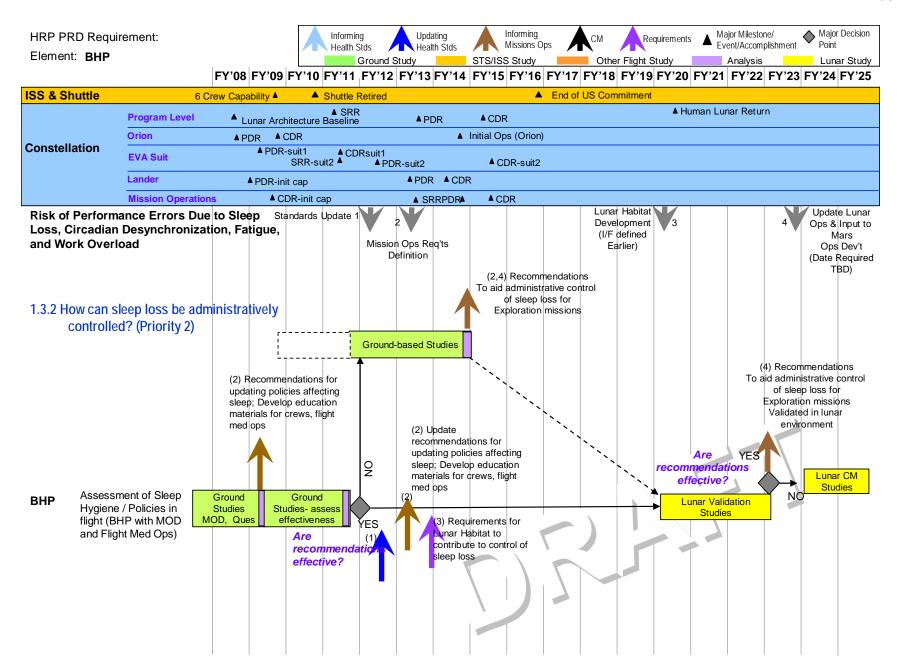
The activity will be conducted in various ground laboratory studies and the blue light (and/or bright light) requirements will be validated in analogs that provide an operational tempo similar to spaceflight, such as NEEMO, MPL, or actual testing during MOD ground support operations. Other analogs offering isolation and lighting challenges, such as Antarctica or HMP will be utilized also if feasible. Involves collaboration with SHFH.

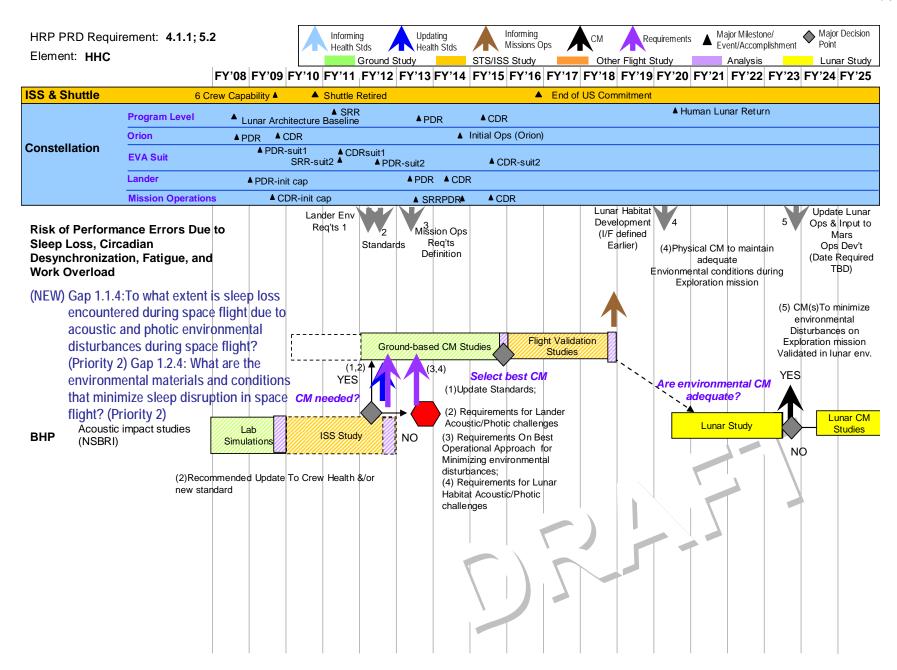
Project/Organization Responsible for Implementation of Activity:

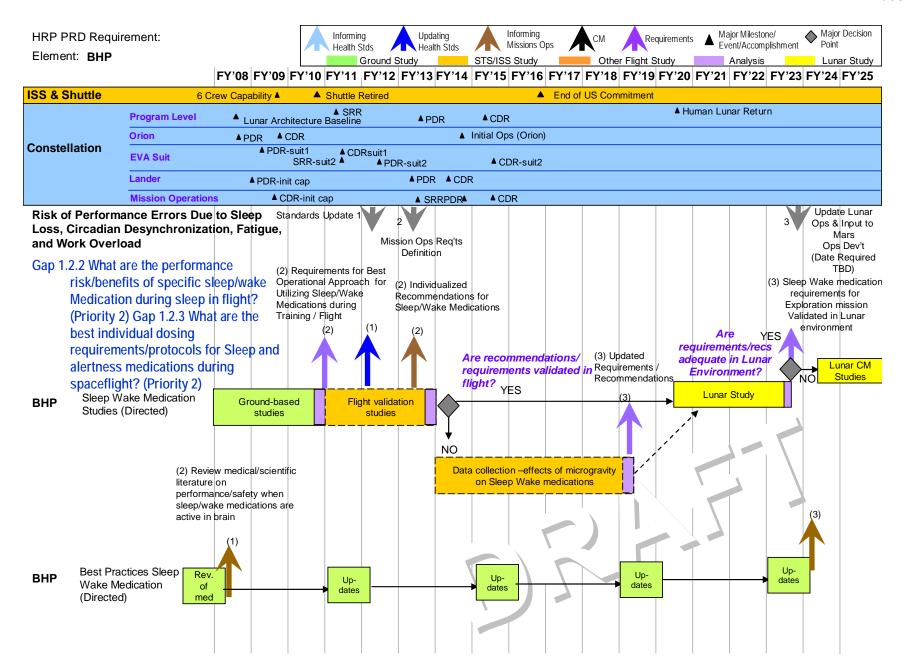
Directed studies with NSBRI

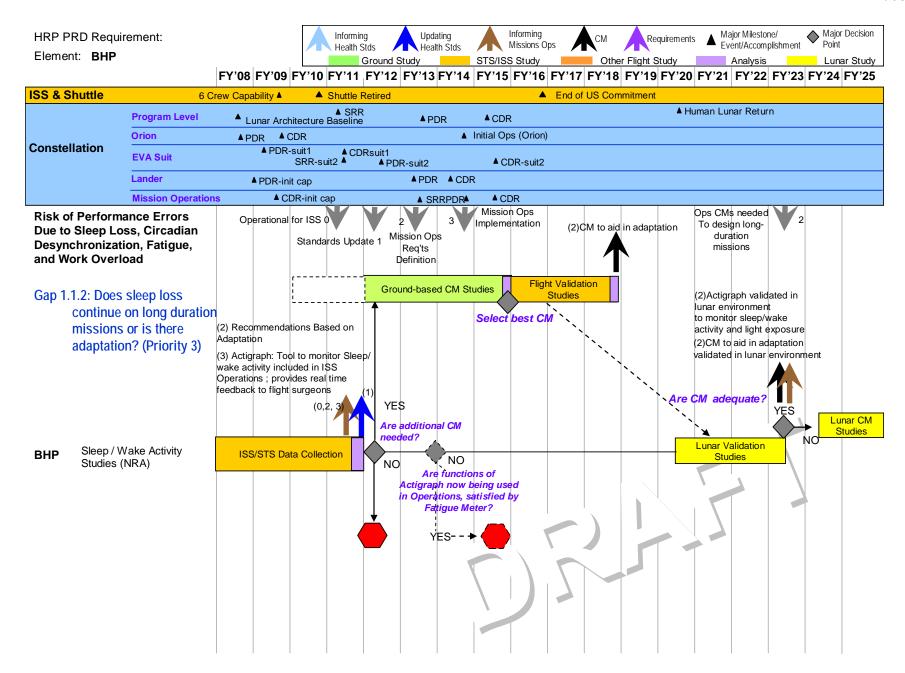


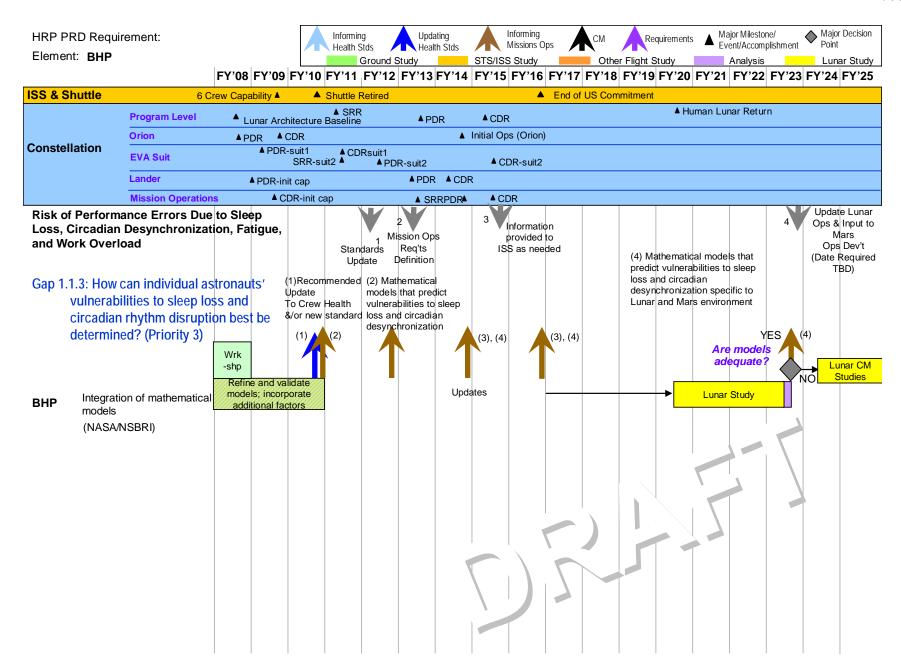


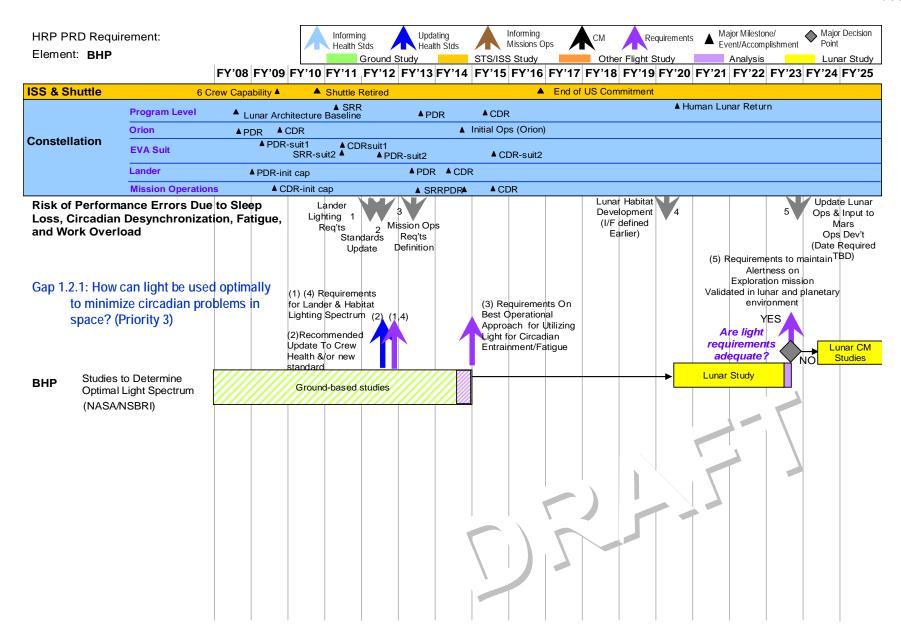












28.0 RISK OF OPERATIONAL IMPACT OF PROLONGED DAILY REQUIRED EXERCISE -D X D

Muscle atrophies in microgravity and strength decreases. Currently, significant daily time is scheduled to crew exercise. Making the exercise more efficient may allow similar beneficial effects to be achieved more simply, and in shorter time, which would provide more crew time for operational support. Benchmarking crew strength requirements, and testing exercise equipment and regimens against these benchmarks, will promote the development of more efficient, yet equally safe, exercise regimens.

Operational Relevance and Risk Context

At present the crews aboard ISS spend up to two hours a day exercising. However, neither the exercise regimens, nor the measurement of the efficacy of these regimens have been standardized. In flight exercise prescriptions have not been systematically evaluated. It is possible that the amount of time spent exercising is more than is required to maintain strength and fitness levels. If more efficient protocols can be developed, then crew time can be recovered for other mission activities. Until in-flight measurements of VO₂max, and muscle mass, strength and endurance are accurately measured, the current exercise prescription cannot be evaluated, and optimization of prescriptions may not be possible.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Desirable to Quantify and Reduce Prior to the Mars Mission.

Gaps

M2: What is the current status of in-flight and post-flight exercise performance capability? What are the goals/targets for protection with the current in-flight exercise program?

M7: Can the current in-flight performance be maintained with reduced exercise volume?

M8: What is the minimum exercise regimen needed to maintain fitness levels for tasks?

M9: What is the minimum set to equipment needed to maintain those (M8) fitness levels?

CV2: In-flight and immediate post-flight VO2 max is unknown.

Activity:

ISS ARED Muscle Function Study

See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gaps 7-9

Activity:

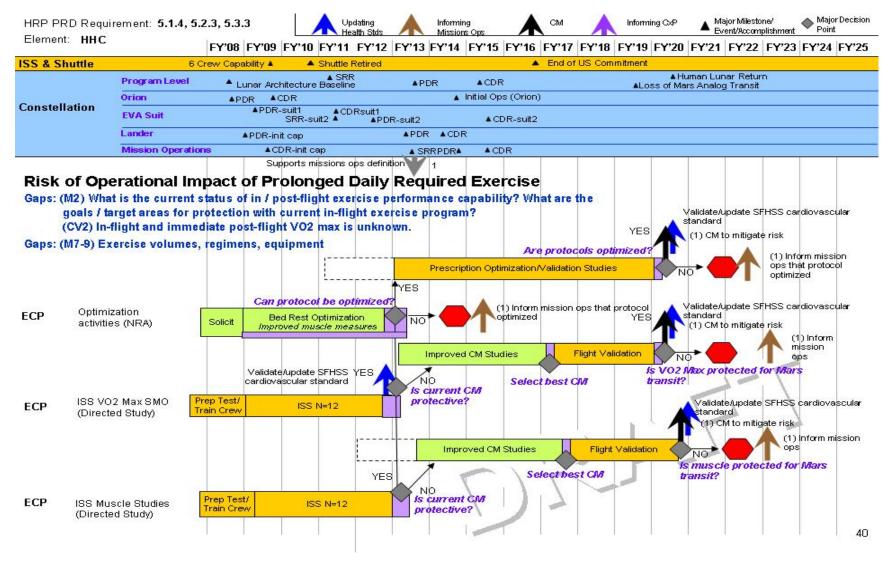
Bed Rest Exercise Countermeasures Optimization

See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gaps 7-9

Activity:

ISS/VO₂max Study

See Risk of Unnecessary Operational Limitations Due to Inaccurate Assessment of Cardiovascular Performance – Gap CV2



29.0 RISK OF UNNECESSARY OPERATIONAL LIMITATIONS DUE TO INACCURATE ASSESSMENT OF CARDIOVASCULAR PERFORMANCE -D X D

Current in-flight indicators of cardiac performance may not accurately reflect astronauts' cardiovascular performance. Making operational decisions based on inaccurate cardiac performance measures may unnecessarily restrict crewmembers for critical activities or, more seriously, could subject crewmembers to activities for which they are not physically prepared. Accurate measurement of crewmember aerobic capacity can eliminate this risk.

Operational Relevance and Risk Context

In-flight VO₂ max measurements should be collected to determine cardiac performance. These measurements will allow medical operations personnel to better determine if the crew is capable to completing various mission tasks.

Priority:

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Desirable to Quantify and Reduce Prior to the Mars Mission.

Gaps

CV2: Unknown in-flight and immediate post-flight VO₂ max

Activity:

ISS/VO₂max Study

The measurement of aerobic capacity (VO₂max) and cardiac output will be performed during and after long-term spaceflight.

Product/Deliverables:

Results from this study will determine if the current countermeasures adequate and need only optimization (e.g., reduced volume, time) or if improved countermeasures and flight validation studies are needed.

Required Delivery Milestone:

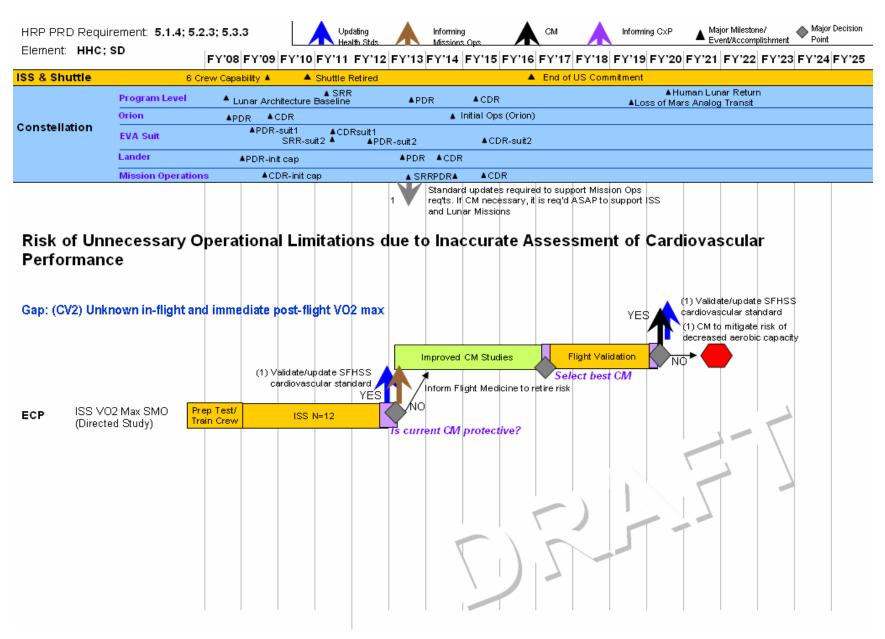
The SFHSS cardiovascular standard will be validated/updated in 2013; if no countermeasure is necessary, flight medicine will be informed in 2013; deliver countermeasure, if necessary, in 2020; and update the SFHSS cardiovascular standard in 2020. All products are required by FY13 to support mission operations requirements development.

Required Platforms:

ISS is required for the initial flight study; ground-based flight analog bed rest is required if improved countermeasures are needed. The improved countermeasures will be validated on board the ISS.

Project/Organization Responsible for Implementation of Activity:

ECP – via directed study



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30.0 RISK OF BONE FRACTURE -D X D

Bone mineral loss occurs in microgravity due to unloading of the skeletal system, with average loss rates of approximately 1% per month. It is unclear whether this bone mineral density will stabilize at a lower level, or continue to diminish. It is also unknown if fractional gravity, present on the moon and Mars would mitigate the loss. This level of bone loss does not create an unacceptable risk of fractures for ISS missions, but longer missions could create higher fracture risk. The risk of fracture during a mission cannot be accurately estimated until mechanisms and probabilities of bone overloading during the missions are understood. Mission-related bone loss cannot be corrected by post-mission rehabilitation; crewmembers could be at greater risk of osteoporosis-related fractures in later life. Greater understanding of the mechanisms of bone demineralization in microgravity is necessary to frame this risk, as well as to understand how current and future osteoporosis treatments may be employed.

Operational Relevance and Risk Context

DXA scans of astronauts and cosmonauts following long duration missions reveal an averaged monthly rate of BMD loss at 1-1.5% bone mass in lower limbs, hip, spine and pelvis. QCT further delineates a greater percentage loss in the cancellous bone compartment, relative to loss in cortical bone, as well as geometric changes in the proximal femur. Temporal recovery of preflight bone mass exceeds the duration of spaceflight exposure with a 50% restoration on the order of 200-250 days, based on a mathematical fit of postflight DXA BMD measurements. Thus, the recovery model, based upon fitted data, suggest that substantial recovery could occur in about 3 years following a 6 month flight. The fracture risk for bone is related to the ratio of applied load to bone to the fracture load of bone. The most critical work needed for assessment of this risk is measures of inflight changes in bone mass over the course of ISS missions so that temporal changes in bone mass can be predicted during longer missions. Those data will provide a basis for evaluating whether the expected loads/torques to the bones during a mission will exceed the failure load of bone (i.e., fracture load). This knowledge will drive mission operations planning and postflight rehabilitation.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Desirable to Quantify and Reduce Prior to the Mars Mission.

Gaps

B1: Is bone strength completely recovered with recovery of BMD?

B2: What new technologies are available for in-flight fracture diagnosis?

B10: What is the time course of bone demineralization during flights greater than 90 days on ISS and during Lunar Outpost missions?

Activity:

Review of medical records to document the frequency of fracture in long duration crew (Russian, Mir and ISS)

Activity:

Bone Recovery Studies – TBD

See Risk of Accelerated Osteoporosis – Gaps 1 and 10

Activity:

Technology to Monitor Bone Quality Changes – study TBD

See Risk of Accelerated Osteoporosis – Gaps 1 and 10

Activity:

Expanded Analysis of Bone Turnover – study TBD

See Risk of Accelerated Osteoporosis – Gaps 1 and 10

Activity:

Vertebral Compression Fractures – Directed Study TBD

A flight study will be conducted to assess whether or not there are postflight vertebral compression fractures following long duration missions. This study will share data with Medical Requirement-035L Bone Densitometry.

Product/Deliverables:

If the results of this flight study indicate that vertebral fractures are a true flight issue, clinical countermeasures may be developed and implemented.

Required Delivery Milestone:

Validation / updates to the health standard will occur in FY11 which will affect the Constellation Program SRR in FY11. If countermeasure development studies are required, mission operations will be informed in FY14 on lander and vehicle load constraints and a validated countermeasure will be delivered in FY18; both are required in FY14 for lander CDR and mission operations requirements development.

Required Platforms:

ISS is required as the Mars transit analog for initial work and countermeasure validation.

Project/Organization Responsible for Implementation of Activity:

NxPCM – via directed study

N5: Can a single test monitor net bone calcium changes?

Activity:

Calcium Isotope Study – TBD

B12: How does the EVA suit influence characteristics of falling?

Activity:

Center of Gravity Studies

Conduct a series of studies to systematically understand the role of suit center of gravity (CG) on human performance and stability in partial gravity environments. Conduct a parabolic flight study to identify the location and measure the forces imparted to the body due to falling in an EVA suit.

Prototype suits will also be evaluated.

Product/Deliverables:

Recommendations for suit design to avoid falling

Data for fall frequency and contact forces model

Required Delivery Milestone:

Work will be complete by FY10 to provide inputs to Configuration 2 suit Systems Requirements Review. Follow-on studies will be performed as needed to evaluate prototype suits.

Required Platforms:

Partial Gravity Simulator (Pogo), Neutral Buoyancy Laboratory (NBL), NEEMO, parabolic flight

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

Activity:

Model Fall Frequency

Analyze Apollo EVA video to estimate percentage of falls. Create model to analyze worst case falls, such as from a ladder. Combine results with data collected in CG and fall forces study to develop model of fall frequency and contact forces based on surface ops concepts.

Product/Deliverables:

Model of fall frequency and contact forces based on concept of mission operations and operations concepts to limit falls

Required Delivery Milestone:

Initial modeling will be complete by FY11 to provide inputs to Surface Ops Systems Design Review. Model will be updated based on results from evaluation of prototype suites. Additional analysis will be performed as needed.

Required Platforms:

Statistical analysis and modeling capability

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

B13: What are acceptable load and torque ranges a crewmember can experience during a specific mission?

Activity:

Quantification of Joint Loads

Analyze inverse dynamics data collected during suit tests conducted for EPSP1 and other ground studies to define joint load and torque ranges experienced during nominal and off-nominal EVA

Product/Deliverables:

Quantification of joint load and torque ranges

Required Delivery Milestone:

TBD

Required Platforms:

Biomechanics analysis software packages

Project/Organization Responsible for Implementation of Activity:

EPSP – via directed study

B11: What are the effects of radiation on bone?

Activity:

The HHC Element will negotiate with the Space Radiation Project (SRP) to quantify the effects of radiation on bone.

Product/Deliverables:

Required Delivery Milestone:

Required Platforms:

Project/Organization Responsible for Implementation of Activity:

SRP

B15: Can exercise hardware and protocol be designed to provide loads necessary to stimulate bone formation?

Activity:

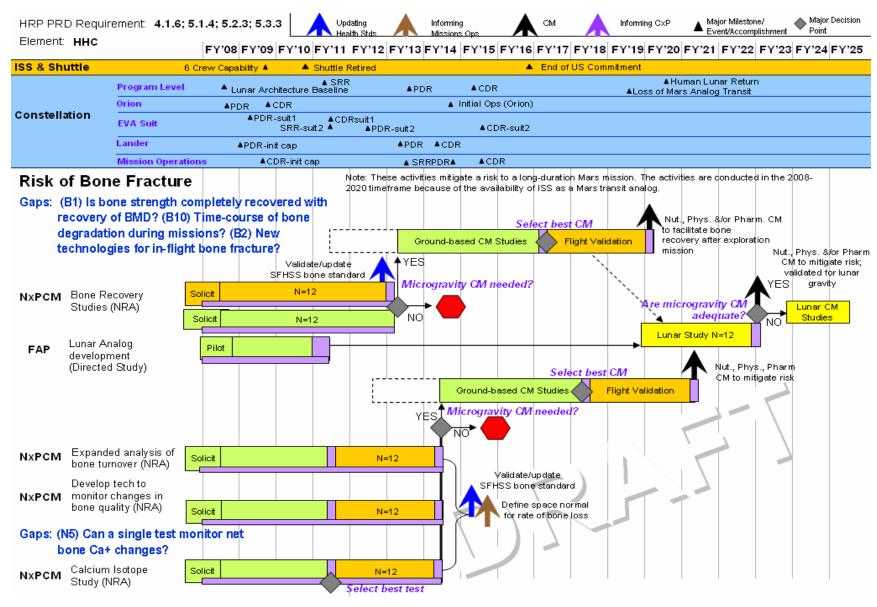
Bed Rest Exercise Countermeasures Optimization

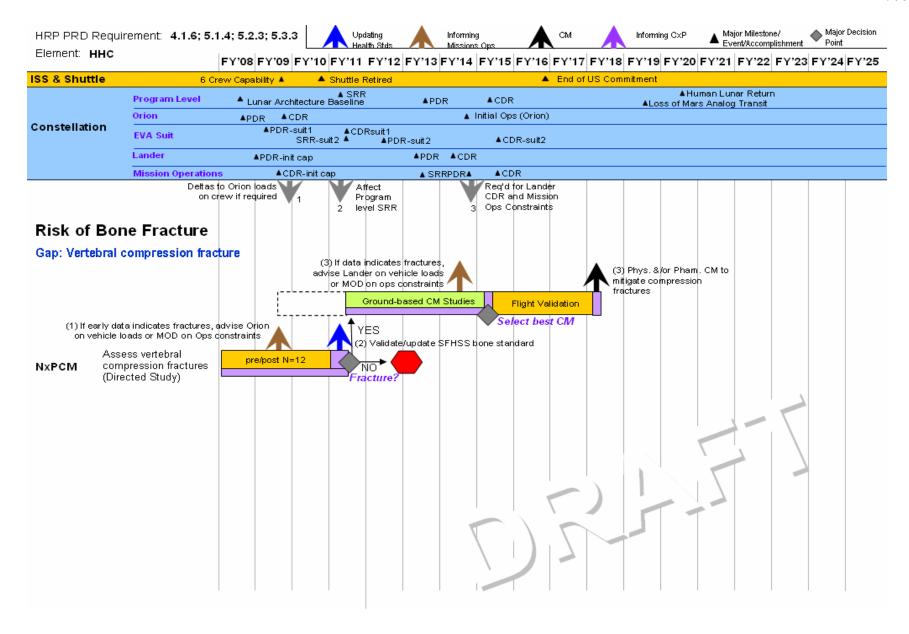
See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gaps M7-9

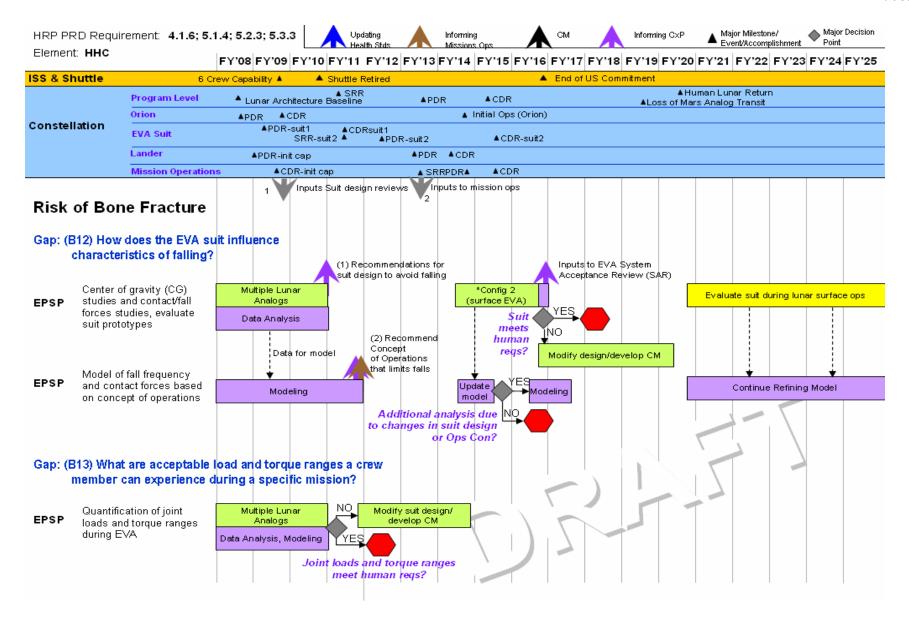
Activity:

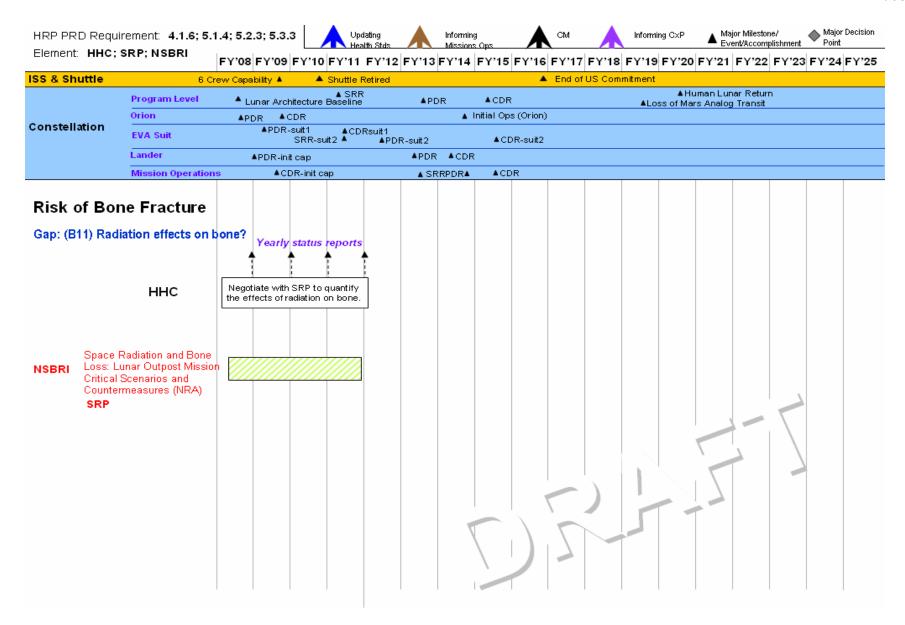
ISS ARED Muscle Function Study

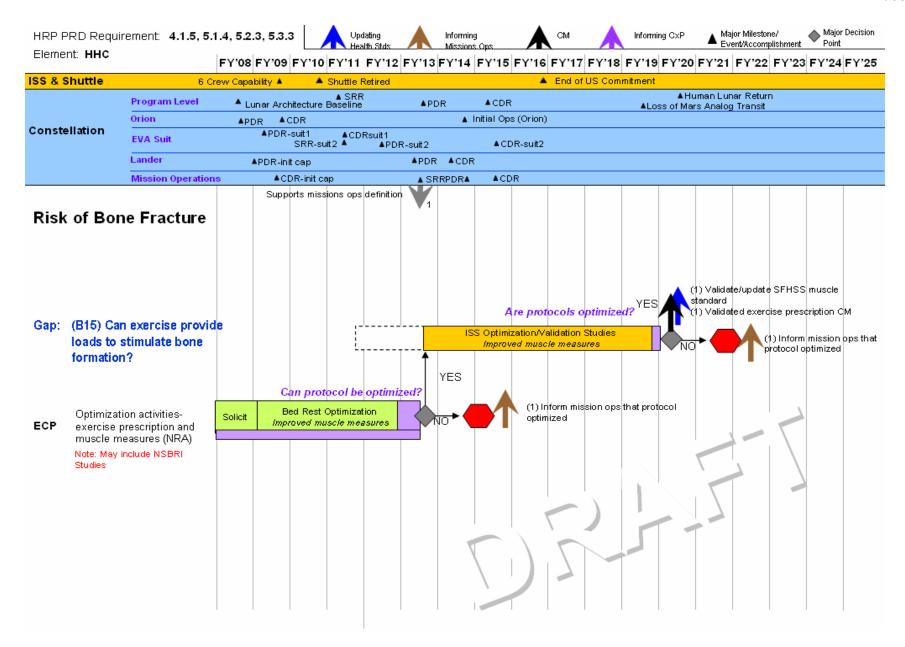
See Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – Gaps M7-9











31.0 RISK OF RENAL STONE FORMATION -D X D

Kidney stone formation and passage has the potential to greatly impact mission success and crewmember health for long-duration missions. Alterations in hydration state (relative dehydration) and bone metabolism (increased calcium excretion) during exposure to microgravity may increase the risk of kidney stone formation and it is unclear which mitigation strategy would be the most effective.

Operational Relevance and Risk Context

Countermeasures for renal stone formation must be validated prior to Mars exploration missions because of reduced level of care and prolonged evacuation time. Inflight monitoring may be developed and instituted so that crew members will have a means to track their renal stone markers.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Desirable to Quantify and Reduce Prior to the Mars Mission.

<u>Gaps</u>

B5: What is the current state of knowledge regarding renal stone formation?

B6: What are the contributing factors other than loss of bone mineral density?

B7: Is it necessary to increase crew fluid intake and, if possible, to what extent will it mitigate stone formation?

B8: Do pharmaceuticals work effectively in spaceflight to prevent renal stones?

B9: What is the frequency of post-flight stone formation; the incidence and types of stones; and the time course of stone formation? How does stone formation correlate with food intake and hydration status?

B16: Can inhibitors of stone formation be sufficiently provided through dietary sources?

N13: Can renal stone risk be decreased using nutritional countermeasures?

Activity:

Data Mining for Incidence of Renal Stone Formation Following Spaceflight

The evidence establishing the risk factors and/or the likelihood of risk occurrence for renal stone formation is either known or in-progress. This study will compile data related to the risk of renal stone formation from medical data and raw research data used for previously published reports) and determine primary and other risk factors for renal stone formation, particularly regarding the types of stones formed (to identify the

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specific risk factor and appropriate countermeasure), the correlation with diet and the time course for formation.

Product/Deliverables:

Final report of findings; if data (combined with Renal Stone study results) indicate that new or additional countermeasures are required, then ground-based studies will be solicited to find suitable candidate countermeasures. The best of these countermeasures will then be validated through solicited flight studies.

Required Delivery Milestone:

Final report in 2008; inform medical operations of results in 2008; deliver validated countermeasure(s) to mission operations in 2016. If the data indicate there is a valid risk of renal stone development, then a countermeasure to mitigate this risk is required as soon as possible.

Required Platforms:

If further countermeasures are needed, the bed rest ground analog is required to demonstrate countermeasure efficacy. ISS is required as the Mars transit analog for countermeasure validation if new countermeasures are developed.

Project/Organization Responsible for Implementation of Activity:

NxPCM – directed study

Activity:

Renal Stone Risk During Spaceflight: Assessment and Countermeasure Validation

The studies planned in this investigation will not only provide a better understanding of the stone-forming risk crewmembers experience during and after space flight, but will take the next step to test the efficacy of potassium citrate as a countermeasures to reduce this risk. Based on the known increased risk crewmembers experience, it is imperative that countermeasures to reduce or alleviate this risk are developed and tested.

Product/Deliverables:

Final report of findings. If data (combined with data mining studies) indicate that new or additional countermeasures are required, then ground-based studies will be solicited to find suitable candidate countermeasures. The best of these countermeasures will then be validated through solicited flight studies.

Required Delivery Milestone:

Final report in 2008; inform mission operations in of findings in 2008; deliver validated countermeasure(s) in 2016. If the data indicate there is a valid risk of renal stone development, then a countermeasure to mitigate this risk is required as soon as possible.

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Required Platforms:

If further countermeasures are needed, the bed rest ground analog is required to demonstrate countermeasure efficacy. ISS is required as the Mars transit analog for countermeasure validation if new countermeasures are developed.

Project/Organization Responsible for Implementation of Activity:

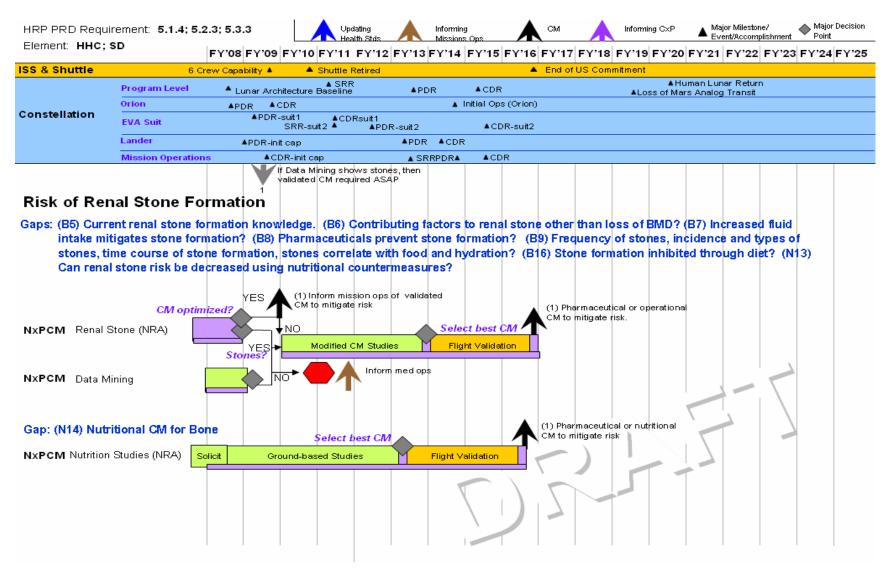
NxPCM - via NRA

N14: What nutritional countermeasures can be used to mitigate bone loss?

Activity:

Nutrition Countermeasures for Bone – study TBD

See Risk of Accelerated Osteoporosis – Gap N1



32.0 RISK OF URINARY TRACT DYSFUNCTION -D X D

Multiple cases of urinary retention and subsequent urinary tract infections have been observed during short duration space flight, chiefly among females. It is not clear why exposure to microgravity adversely affects the functioning of the urinary tract. Further research into this area could explain this phenomenon, and assist with the clinical management of these cases.

Operational Relevance and Risk Context

Urinary tract infections have impacted mission operations in the past. It is not known if a combination of altered immune function and urinary tract dysfunction might work together to cause these infections to become intractable during longer missions. Such an occurrence could have a large and impact on the mission and on crew health.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Desirable to Quantify and Reduce Prior to the Mars Mission.

Gaps

MO1: Determine how and why exposure to microgravity adversely affects urinary tract function.

Activity:

Data Mining Activities

Data review activities are required to determine any known issues associated with urinary tract infections; this includes literature searches and searching the LSAH database.

Product/Deliverables:

Space normal data to indicate if any known urinary tract issues exist. If issues do exist, the medical operations will be informed in FY09and countermeasures will be delivered in FY15.

Required Delivery Milestone:

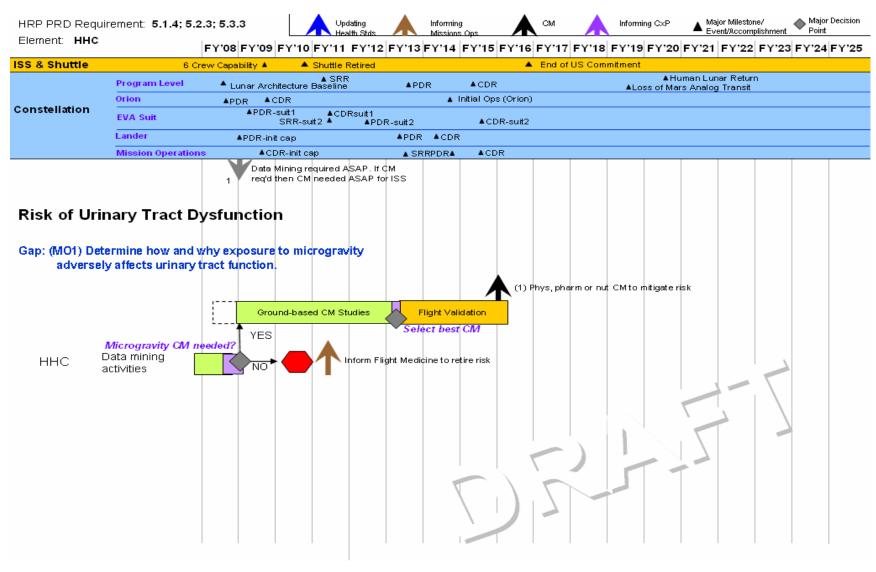
Data mining will occur during FY08 and if the data indicates no risk, flight medicine will be informed by FY09 to retire the risk. Countermeasures to mitigate the risk will be delivered in FY15. Data is required as soon as possible to determine if a countermeasure is required for ISS crews.

Required Platforms:

Ground-based databases initially. If further work is required, ground analogs will be required as well as ISS.

Project/Organization Responsible for Implementation of Activity:

HHC Element



33.0 RISK OF IMPAIRED VISION DUE TO REFRACTIVE VISUAL CHANGES DURING LONG-DURATION SPACEFLIGHT -D X D

Significant changes in visual refraction have been documented among ISS crewmembers. These changes appear to be due to senescent accommodative changes that may be exacerbated by the small volume of spacecraft cabins. Vascular engorgement of retinal support layers also appears to play a role. Not all crewmembers suffer from this problem. Identification of associated risk factors, underlying pathophysiology, and mitigation strategies are necessary for maintaining crew vision during long-duration missions.

Operational Relevance and Risk Context

An understanding of the changes in visual acuity, and countermeasures for the changes, could affect all aspects of mission design, including vehicle and tools design, tasks and procedures, EVA suit design. In addition it is necessary to determine if these changes will have long term effects on crew health.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Desirable to Quantify and Reduce Prior to the Mars Mission.

Gaps

MO2: Determine the associated risk factors, underlying pathophysiology, and mitigation strategies for maintaining crew vision.

Activity:

Data mining Activities

Data mining activities are required to determine any known issues associated with vision problems; this includes literature searches and searching the LSAH database. If issues exist, further ground-based countermeasure development studies will be conducted followed by flight validation studies.

Product/Deliverables:

Space normal data to indicate if any known visual acuity issues exist. If issues do exist, the medical operations will be informed in FY09 and countermeasures will be delivered in FY15.

Required Delivery Milestone:

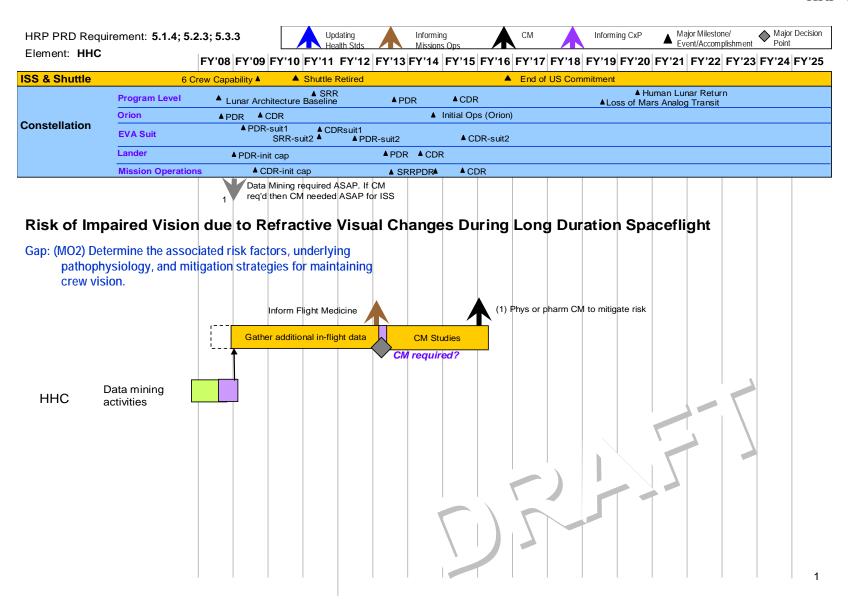
Data mining will occur during FY08 and if the data indicates no risk, flight medicine will be informed by FY09 to retire the risk. If additional flight data is required, those studies will take place in 2009-2013 and countermeasures to mitigate the risk will be delivered in FY15. Data is required as soon as possible to determine if a countermeasure is required for ISS crews.

Required Platforms:

Ground-based databases initially. If further work is required, then ISS is needed.

Project/Organization Responsible for Implementation of Activity:

HHC Element



34.0 RISK OF ADVERSE HEALTH EFFECTS DUE TO EXPOSURE TO HYPOXIC ENVIRONMENTS -D X D

Spacecraft designers strive to maintain a normal terrestrial atmosphere for crewmembers; however, frequent EVA's necessitate decreasing the atmospheric nitrogen levels to decrease the risk of decompression sickness. Decreasing nitrogen partial pressure without decreasing oxygen partial pressure creates a significant fire risk. Concerns exist whether crew performance could be adversely affected if cabin oxygen pressures are decreased. Research into human performance at lower oxygen partial pressures could lead significant safety improvements in the design of future vehicles and missions.

Operational Relevance and Risk Context

It has been shown that in the South Pole (elevation of 10,000 feet above sea level) people get mountain sickness. People may have cognitive and/or exercise issues living at the South Pole elevation. There is a gap in our knowledge base for this issue; data mining activities are required to determine any known issues associated with hypoxic environments. This risk is more similar to risk mitigation.

Priority

Lunar Outpost Mission: Desirable to Quantify and Reduce Prior to the Lunar mission.

Mars Mission: Desirable To Quantify and Reduce Prior to the Mars Mission.

Gaps

MO4: Determine whether crew performance is adversely affected if cabin oxygen pressures are decreased.

Activity:

Data Mining Activities

Data mining activities are required to determine any known issues associated with hypoxic environments; this includes literature searches and searching the LSAH database. If issues exist, further ground-based countermeasure development studies will be conducted followed by flight validation studies.

Product/Deliverables:

Space normal data to determine if there are any known issues with hypoxic environments. If issues do exist, the medical operations will be informed in FY09 and countermeasures will be delivered in FY15

Required Delivery Milestone:

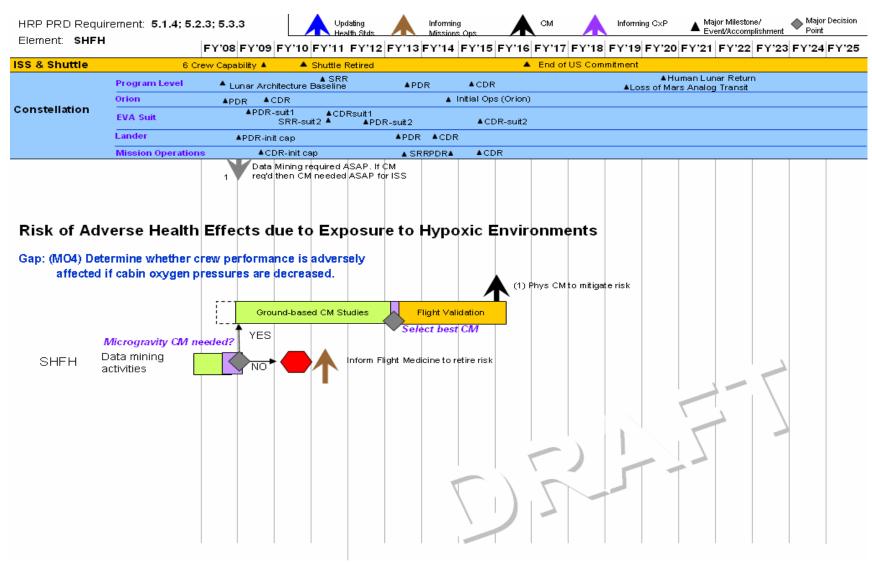
Data mining will occur during FY08 and if the data indicates no risk, flight medicine will be informed by FY09 to retire the risk. Countermeasures to mitigate the risk will be delivered in FY15. Data is required as soon as possible to determine if a countermeasure is required for ISS crews.

Required Platforms:

Ground-based databases initially. If further work is required, ground analogs will be required as well as ISS.

Project/Organization Responsible for Implementation of Activity:

SHFH Element



APPENDIX A: TBR & TRL

In this version of the IRP, some gaps and activities are noted as To Be Reviewed (TBR). The Science Management Panel, along with Program Management and the appropriate Element Management will conduct a review in CY2008 of these activities to determine the proper representation of the gap or activity and the criticality to the risk. The table to follow is a list of the current TBRs represented in this document (IRP-1).

In some cases, due to the low TRL nature of some NSBRI studies, the direct connectivity or relevancy of the item to the risk has not been fully established. This version of the IRP identifies research and technology projects that are either heritage studies from previous selections or are low TRL studies. These studies are labeled To Be Reviewed (TBR-NSBRI) meaning that a thorough review for relevancy to the risk will be conducted in CY2008. Reference the figure at the end of this section for a visual definition of TRLs.

Further, the IRP currently contains some studies that are conducted under Small Business Innovative Research (SBIR) awards. These studies are typically low TRL investigations, and are labeled TBR-SBIR meaning that a review for relevancy of these items will occur in CY2008.

TBR Table

Table #	Name of Gap/Activity	
Inability to Adequately Treat an Ill or Injured Crew Member		
TBR-1 (SBIR)	(Activity) Wearable Health Monitoring Systems	
TBR-2 (NSBRI)	(Activity) Guided High Intensity Focused Ultrasound (HIFU) for mission critical care	
TBR-3 (NSBRI)	(Activity) Prototype testing for non-invasive determination of intracranial pressure	
TBR-4 (NSBRI)	(Activity) Improved bubble detection for EVA	
Risk Factor of Inadequate Nutrition		
TBR-5	(Activity) The HHC Element will collaborate with the Space Medicine Division (SD) to determine how various countermeasures impact nutrition.	
Risk of Inadequate Food System		
TBR-6	(Gap) AFT3: What are the psychosocial requirements for the food system for different mission lengths?	
TBR-7	(Activity) Variety, acceptability, and usability requirements development.	

TBR-8	(Gap) AFT6: How can the mass and volume of the Lunar food system be reduced and how can it serve as a test bed for future Mars missions?	
TBR-9	(Activity) Food processing vs. packaged food system trade study.	
Risk of Behavioral and Psychiatric Disorders		
TBR-10 (NSBRI)	(Activity) Refine and Validate Tool for Early Detection and Mitigation of Depression	
Risk of Performance Errors due to Poor Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation		
TBR-11	(Gap) 2.3.1 What are the best methods for training crews for maintaining cohesion and optimal performance during exploration missions?	
TBR-12	(Gap) 2.3.2 What are the best methods and tools for selecting and composing crews for optimal team performance during exploration missions?	

<u>Definition of Technical Readiness Levels (TRL)</u>

